

## Records Responsive to EPA-2017-007542

Please note, copying and pasting each link into Google Chrome works best for accessing these records.

1. The AUDIO recording of the public meeting (via teleconference) held by the Office of Air and Radiation (OAR) on April 24, 2017.
  - a. Transcription of the OAR Meeting: <https://www.regulations.gov/document/EPA-HQ-OA-2017-0190-13898>
2. The AUDIO recording of the two public meetings held by the Office of Chemical Safety and Pollution Prevention about Toxic Substances Control Act (TSCA) (held 9 AM – noon) and lead (held 1 – 4 PM) on May 1, 2017.
  - a. Transcription of the TSCA Meeting: <https://www.regulations.gov/document/EPA-HQ-OA-2017-0190-22478>
  - b. Transcription of the Lead Meeting: <https://www.regulations.gov/document/EPA-HQ-OA-2017-0190-22477>
3. The AUDIO recording of the Pesticide Program Dialogue Committee (PPDC) meeting held by the Office of Chemical Safety and Pollution Prevention about pesticides from 8:30 – noon on May 4, 2017.
  - a. Transcription of the PPDC Meeting – Day One: Pages 2-239, below.
  - b. Transcription of the PPDC Meeting – Day Two: Pages 240-366, below.
4. The AUDIO recording of the public meeting held by the Office of Land and Emergency Management (OLEM) on May 9, 2017
  - a. AUDIO File of the OLEM Meeting: <https://www.regulations.gov/document/EPA-HQ-OA-2017-0190-29466>

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UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

DAY ONE - MAY 3, 2017

Conference Center - Lobby Level

2777 Crystal Drive  
One Potomac Yard South  
Arlington, VA 22202

## P R O C E E D I N G S

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MR. KEIGWIN: Welcome, everybody. Good morning. Thanks for coming. We've got a very busy day ahead of us, so we look forward to the discussions.

I first want to introduce to everybody Wendy Cleland-Hamnett. She's the Acting Assistant Administrator for the Office of Chemical Safety and Pollution Prevention. She has a couple of welcoming remarks.

MS. CLELAND-HAMNETT: Thanks, Rick, and good morning, everyone. I'm really happy to be here to welcome you all to this PPDC meeting. As Rick said, my name is Wendy Cleland-Hamnett. My position of record in the Office of Chemical Safety and Pollution Prevention is Principal Deputy Assistant Administrator, which is a career position.

I'm the Acting Assistant Administrator now, presumably until we get a presidential appointee in the Assistant Administrator position. So, I've been doing this since January 20th, or 21st, right after Jim Jones left. I just started as the Principal DAA back last October 1st. But I've worked in the Office of Chemical Safety and Pollution Prevention since 2004

1     this round. I had worked in the office way back when  
2     at the beginning of my EPA career.

3             Before I became the DAA last October, I was  
4     the Office Director for the chemical side of the  
5     office. So, I worked on TSCA reform and implementing  
6     the older version of TSCA prior to that. So, I am  
7     familiar with the pesticides program, although I am  
8     learning a lot. Have been learning a lot since last  
9     October about some of the specific issues and projects  
10    that people in the OPP have been working on.

11            It's really been a great experience meeting  
12    the great people who work here, the management team,  
13    learning the issues, meeting many of you and your  
14    colleagues in the stakeholder community. So, I've  
15    really enjoyed this, and I look forward to continuing  
16    to work in this area as acting and then, hopefully  
17    before too long, back as the Deputy Assistant  
18    Administrator. So, again, welcome.

19            I actually have attended a few PPDC meetings  
20    before when I was Office Director in the toxics  
21    program. I came to a few to see how you all work  
22    together, because we have thought about creating a  
23    similar kind of group for the chemicals program, once  
24    we get our framework together to start implementing  
25    the reforms to TSCA. I think a couple of times since

1       then I've been to the PPDC, but the first time in this  
2       particular role.

3               I just think that you play a very critical  
4       part in what the pesticides program does.

5       Transparency is very important, hearing from all of  
6       the stakeholders who have an interest in the  
7       pesticides program on behalf of your sort of  
8       constituencies that you represent, formally or  
9       informally, and also just on behalf of the American  
10      public in terms of protecting human health and the  
11      environment, protecting the food supply, public  
12      health, all of the things that -- the products that we  
13      work on here in the pesticides program are meant to  
14      provide to the American public, as well as protecting  
15      human health and the environment.

16             I know that it's a huge time commitment to  
17      be on a committee like this, to prepare, to come to  
18      the meetings, to follow up from the meetings, to be on  
19      the working groups, and so forth. So, I can't tell  
20      you how much I appreciate that and Rick and the people  
21      in the program appreciate that.

22             So, one of my goals during this period that  
23      I'm the Acting Administrator is to make sure that we  
24      keep doing what we need to do, that we keep focused on  
25      the mission here in pesticides on the chemical side,

1     that we keep, you know, the registration process  
2     moving along, the registration review process moving  
3     along, the work on the science moving along, while we  
4     are helping the new leadership in the Agency to  
5     transition in and figure out what they need to focus  
6     on, want to focus on, and so forth.

7             So, I am here to help with that.

8     Unfortunately, I won't be able to stay with you  
9     through the day today, but if you don't know where to  
10    find me, Rick can tell you where to find me. So, you  
11    know, I'm open to e-mails, phone calls, meeting  
12    requests, and so forth. If any of you would like to  
13    follow up on particular issues, I am happy to do that,  
14    as I know the folks over here in the pesticides  
15    program are as well.

16            So, if that does it, thank you so much. I  
17    look forward to hearing what you're all talking about.  
18    I'll try to pop back over here today or tomorrow to  
19    catch up on what's going on, but I'll also get filled  
20    in by folks here. So, thanks very much. Hope you  
21    have a good day and get to enjoy the outdoors at lunch  
22    time. Nice weather for DC itself. Two weeks a year  
23    we get this kind of weather. Thanks very much.

24            MR. KEIGWIN: Thanks, Wendy.

25            So, again, welcome to everybody. We do very

1 much appreciate all the work that you all put in  
2 outside as part of the work groups. Having you all  
3 give us advice on important matters facing the program  
4 I think really helps us to advance our work working  
5 with you to, as Wendy said, protect public health and  
6 the environment.

7 Before we go around, I want to give folks a  
8 few updates on what has been happening in the office  
9 since our last meeting. But I first want to recognize  
10 some of the people on the committee who this will be  
11 most definitely their last meeting, because some of  
12 you are term limited as part of the FACA requirements.

13 So, among those are Cheryl Cleveland, Beth  
14 Law, who wasn't able to participate today, Ray  
15 McAllister, Jake Vukich, Virginia Ruiz, Valentin  
16 Sanchez, Captain Calvert, who is not here today, Mike  
17 Kashtock, who is not here today, Robyn Gilden, Marc  
18 Lame, Wayne Buhler, Tom Delaney, Doug Hanks, who I  
19 believe is going to participate over the phone, and  
20 Gabrielle Ludwig. So, thank you all again.

21 Those people have been on the committee now  
22 I think for almost six years, so we really appreciate  
23 all the efforts and all of your contributions to the  
24 work here. I know, even though you won't be on the  
25 committee for the foreseeable future, we'll still be

1 hearing from you and contributing in other ways.

2 Membership did close for the next cycle of  
3 the PPDC on April 21st. We had a very high interest  
4 in participating on the committee moving forward. So,  
5 thanks to the current members who were eligible to  
6 reapply for reapplying. We're going through the  
7 process now of, you know, reviewing the applications.  
8 We'll make our recommendation to Wendy. Then Wendy  
9 will take the OCSPP recommendation forward within the  
10 Agency. Hopefully, in time for our fall meeting,  
11 we'll have the new PPDC up and running. So, that's  
12 the update there.

13 I want to quickly go through the agenda.  
14 This one is obviously a little bit different than  
15 other PPDC meetings because we're trying to squeeze a  
16 lot of things into day one, so that we can use our  
17 session tomorrow to focus on the regulatory reform  
18 efforts as part of implementing President Trump's  
19 executive order on the regulatory agenda. So, we're  
20 going to move pretty fast today.

21 So, we'll first soon go around for  
22 introductions of all the PPDC members. Then we have a  
23 session on pollinator protection. We have a session  
24 on biotechnology. We'll break for lunch. Then, in  
25 the afternoon, we'll provide an update on some of our



1 efforts to implement some 21st century toxicology  
2 techniques.

3 We have a short Q&A session on some topics  
4 that we had heard from you all that you wanted to hear  
5 some updates from us. Then we'll have a report back  
6 after the break from the incidents workgroup. Then  
7 we'll wrap things up with a presentation from Arnold  
8 and his team on vector management and Zika. Then  
9 there will be an opportunity for public comment at the  
10 end.

11 As I mentioned, tomorrow we will do our  
12 regulatory reform meeting. There will be a different  
13 configuration for tomorrow's meeting. We're not going  
14 to sit around a hollow square. It will be more of a  
15 theater style because we wanted to be able to allow as  
16 many people to participate as possible. But for PPDC  
17 members, we'll have some space reserved for you all up  
18 front.

19 So, the first half of tomorrow's meeting  
20 will be you all, and then the second half will be from  
21 the public. I think we have upwards of 15 or 20  
22 people from the public who will be participating with  
23 public comments either in person or over the phone.

24 We are starting a little bit early tomorrow.  
25 We're starting at 8:30. I know how challenging it is

1 to get through security in this building, and with  
2 even more people being here. I think we have several  
3 hundred people who are registered to participate in  
4 person or observe in person. We'll remind you at the  
5 end of the day, but please plan accordingly for  
6 tomorrow so that we can get through all the public  
7 comments.

8 So, in terms of what's been going on in the  
9 Office of Pesticide Programs since our last meeting --  
10 I think the first thing I should probably point out is  
11 the departure of Jack Housenger, who is a huge loss to  
12 OPP. I think Arnold and I knew how much he did, or  
13 thought we knew how much he did. Now that he's gone,  
14 we appreciate everything that he did even more because  
15 now we're trying to divide it up amongst the two of  
16 us. So, Jack carried a very heavy load for this  
17 program, and he is sorely missed.

18 Before he left, however, he left us in a  
19 good place. We selected three new permanent division  
20 directors for the Office of Pesticide Programs. I  
21 just wanted to introduce those people to you all.  
22 Marietta Echeverria is now the Director of  
23 the Environmental Fate and Effects Division. Wynne  
24 Miller is now the Director of the  
25 Biological and Economic Analysis Division. Mike

1 Goodis is now the Director of the Registration  
2 Division. So, thanks. It's great to have the three  
3 of them in their new positions.

4 We've also been going through -- and I won't  
5 go through all of these, but as part of trying to  
6 rebuild the management team and to provide some  
7 opportunities for career growth and advancement, we've  
8 been rotating a number of people around the program  
9 into the Deputy and the Associate Division Director  
10 slots.

11 So, if you look at the org chart in your  
12 packet, you'll see a lot of names that you're probably  
13 familiar with, but you're like why is that person  
14 there? I'm not used to them being there. Part of it  
15 is to rebuild our capacity and get people experiences  
16 in different parts of the program. I think that's  
17 been a good effort here for them and for us.

18 On the registration front, since our last  
19 meeting, we have registered nine new active  
20 ingredients. That's about half of where we expect to  
21 be by the end of the year, three in the Registration  
22 Division, five in the Biopesticides and Pollution  
23 Prevention Division, and one in the Antimicrobials  
24 Division. We're on track to complete the other 10 or  
25 so decisions by the end of this year.

1           On the registration review side, by our next  
2     meeting, we likely will have hit a very significant  
3     milestone in the re-evaluation program where we will  
4     have by then opened all of the dockets for all of the  
5     active ingredients going through registration review.  
6     We're making very good progress on the scientific  
7     evaluation side.

8           At this point, and I'll focus on  
9     conventional chemicals, we've issued about half of the  
10    draft risk assessments for public comment that we  
11    would expect to issue as part of registration review.  
12    We've issued about 40 percent of the proposed  
13    decisions that need to come forward as part of  
14    completing the re-evaluation program by 2022.

15          So, there's been a lot of effort across the  
16    program to get those things done, and a lot of great  
17    input from you all as we have public comment periods  
18    on the draft risk assessments and the proposed  
19    decisions.

20          Some other highlights to note, we're working  
21    with our colleagues in OPPT, as well as FDA and USDA.  
22    Recently received some advice from the National  
23    Academy of Sciences relative to biotechnology and how  
24    to prepare ourselves for some of the new tools and  
25    some of the new technologies coming forward.

1           This was an important piece of an effort  
2   launched in the last administration, and we suspect  
3   we'll continue as we move forward and as these  
4   technologies continue to be developed as part of the  
5   updates to the coordinated framework and our long term  
6   strategy for biotechnology.

7           Probably, for our next meeting, we'll be in  
8   a position to provide you all with an update on the  
9   SmartLabel effort. I think we've talked about that  
10   initiative here in the past, and we really think this  
11   is an important effort for us to modernize pesticide  
12   labeling, not only for us but for the users of these  
13   products so that they have accurate information in a  
14   more digestible format so that these products are used  
15   in a way that they're intended.

16           We'll get an update today on the pollinator  
17   efforts and the work that the workgroup has been doing  
18   on informing metrics for measuring the success of the  
19   managed pollinator protection plans.

20           And then, finally, I should note the work  
21   that we've been doing with the Services on the pilot  
22   set of chemicals for Endangered Species Act biological  
23   evaluations and biological opinions. A lot of great  
24   work that's been going on with the Services and with  
25   input from USDA to help advance the science in that

1 area.

2 Let me stop there. Maybe we can go  
3 around to introduce who is here, and then we'll go to  
4 the phone for the PPDC members. I'll start to my  
5 left.

6 MR. LAYNE: Hi, good morning, everyone,  
7 Arnold Layne, Deputy Office Director, Pesticide  
8 Programs.

9 MR. STELL: Hi, good morning, Fred Stell  
10 from the Armed Forces Pest Management Board.

11 MR. TAYLOR: Good morning, Donnie Taylor  
12 with the Ag Retailers Association here in Washington,  
13 D.C.

14 MS. FLEESON TROSSBACH: I'm Liza Fleeson  
15 Trossbach, and I'm representing the Association of  
16 American Pesticide Control Officials, or AAPCO.

17 MR. FREDERICKS: Jim Fredericks with the  
18 National Pest Management Association.

19 MS. CLEVELAND: Cheryl Cleveland, BASF, RTP.

20 MS. PALMER: Cynthia Palmer, American Bird  
21 Conservancy.

22 MR. GRAGG: Good morning, Richard Gragg,  
23 Florida A&M University, School of the Environment.

24 MS. JAIN: Good morning, Komal Jain,  
25 American Chemistry Council, the Biocides Panel.

1           MR. BUHLER: Wayne Buhler, and I'm serving  
2   on this board as the overly enthusiastic entomologist  
3   from the East Region to counter my western colleague.  
4   I'm with the Pesticide Safety Education Specialists at  
5   NC State University and representing the American  
6   Association of Pesticide Safety Educators.

7           MS. WILSON: Hi, I'm Nina Wilson with Gowan  
8   Company representing the biological products industry.

9           MR. GJEVRE: Good morning, Eric Gjevre,  
10   Tribal Pesticide Program Council.

11          MS. BURD: Lori Ann Burd, Center for  
12   Biological Diversity.

13          MR. VUKICH: Good morning, Jake Vukich with  
14   DuPont Crop Protection in Wilmington, Delaware.

15          MR. DELANEY: Tom Delaney, Georgia Urban Ag  
16   Council, representing the landscape industry.

17          MS. GILDEN: Robyn Gilden with the  
18   University of Maryland School of Nursing and also the  
19   Alliance of Nurses for Healthy Environments.

20          MS. HOYLE: I'm Sarah Hoyle with the Xerces  
21   Society.

22          MR. WHITTINGTON: Andy Whittington,  
23   Mississippi Farm Bureau Federation.

24          MR. COY: Steven Coy, American Honey

1 Producers Association.

2 MS. LIEBMAN: Good morning, Amy Liebman from  
3 Migrant Clinicians Network.

4 MS. HARRIOTT: Nichelle Harriott, Beyond  
5 Pesticides.

6 MS. BISHOP: Pat Bishop, People for the  
7 Ethical Treatment of Animals.

8 MR. SANCHEZ: Valentin Sanchez with the  
9 Oregon Law Center.

10 MR. MCLAURIN: Good morning, my name is  
11 Allen McLaurin. I'm actually a cotton producer from  
12 North Carolina, but I represent the National Cotton  
13 Council.

14 MR. MCALLISTER: Ray McAllister with Crop  
15 Life America.

16 MS. LUDWIG: Gabrielle Ludwig, Almond Board  
17 of California.

18 MR. LAME: Marc Lame with Indiana University  
19 representing the National Environmental Health  
20 Association.

21 MS. SELVAGGIO: Sharon Selvaggio with the  
22 Northwest Center for Alternatives to Pesticides.

23 MS. GOUGE: Good morning, Dawn Gouge, overly  
24 enthusiastic entomologist from the western side of the  
25 continental U.S. I work on public health pests.



1           MR. KUNKEL: Hi, I'm Dan Kunkel with the IR4  
2     minor use program. We're located at Rutgers  
3     University.

4           MS. RUIZ: Virginia Ruiz, Farmworker  
5     Justice.

6           MR. ALARCON: Walter Alarcon representing CDC,  
7     the SENSOR pesticide program.

8           MS. SHULTZ: Gina Shultz, U.S. Fish and  
9     Wildlife Service.

10          MS. KUNICKIS: I'm Sheryl Kunickis. I'm the  
11     director in the Office of Pest Management Policy at  
12     the US Department of Agriculture.

13          MR. KEIGWIN: I think we have a few members  
14     of the PPDC who are participating via the phone. So,  
15     why don't we go to them. Are there PPDC members  
16     participating via phone? Could you introduce  
17     yourself?

18          MR. BENNETT: Steve Bennett, Consumer  
19     Specialty Products, on behalf of Beth Law.

20          MR. HANKS: Doug Hanks, National Potato  
21     Council.

22          MS. LIANG: Charlotte Liang, U.S. Food and  
23     Drug Administration.

24          MS. COLOPY: Michele Colopy,  
25     Pollinator Stewardship Council.

1           MR. KEIGWIN: We're only asking for  
2     introductions from PPDC members. So, I think the  
3     other person that we thought might be participating is  
4     Louis Jackai. Are you on the phone?

5           (No verbal response.)

6           MR. KEIGWIN: Okay, perhaps he'll join us a  
7     little bit later.

8           A few housekeeping issues before --  
9     registration desk. If you haven't done that yet,  
10    please do so at the break. We need to have that for  
11    purposes of the FACA requirements for the meeting.

12          This is the same mic system that we've had  
13    now for the past couple of meetings. So, just a  
14    reminder, the little red button, if you see it red,  
15    that means it's on. When you're done speaking, please  
16    turn it off. I think I have the ability to turn them  
17    all off, but I'd rather not have to do that.

18          Turn your tent cards up when you want to  
19    speak, and we'll try to get to as many of those cards  
20    as we can. The teleconference line is open, so  
21    hopefully folks on the phone are hearing this well.  
22    Another reason why when you are speaking to use the  
23    mic, so that the people on the phone can hear you. We  
24    do have it set up on a global mute and we'll be  
25    controlling the muting and the unmuting. For people

1     that do want to speak who are PPDC members, we can  
2     unmute your line so that you can speak when we go  
3     around for the discussion within the PPDC.

4             For members of the public that have joined  
5     us today, there is a 15-minute public comment session  
6     at the conclusion of today's meeting. Today's comment  
7     period is to focus on the topics on today's agenda.  
8     Anything related to the regulatory reform pieces is  
9     for tomorrow's discussion. If there's a member of the  
10    public that wants to make a comment today, please sign  
11    up at the registration desk out in the lobby here.

12            Then, one last thing for fire code purposes,  
13    in the event of an emergency, please note that there  
14    is an emergency door at the front of the room here.  
15    And then there are four exits out into the lobby from  
16    this room as well.

17            Any questions?

18            (No verbal response.)

19            MR. KEIGWIN: So, why don't I ask Mike to  
20    come forward and lead our first session on  
21    pollinators.

22            MR. GOODIS: Good morning, my name is Mike  
23    Goodis. I'm the Director of the Registration  
24    Division, Office of Pesticide Programs. And sitting  
25    next to me is?

1 MS. GUILARAN: Hi, I'm Yu-Ting Guilaran,  
2 Director of the Pesticide Re-evaluation Division.

3 MR. GOODIS: So, this segment, I think it's  
4 slated for an hour to talk about pollinators. I think  
5 we're going to start off with just really an update or  
6 report out on some recent activities from EPA on  
7 pollinator-related actions, specifically the acute  
8 mitigation policy, the risk assessment for neonics.  
9 I'll talk a little bit about pollinator protection  
10 plans, too.

11 We want to reserve most of the time for the  
12 managed pollinator protection plan workgroup to report  
13 back on the status and the approach that they're  
14 taking in providing recommendations to the Agency,  
15 looking again at metrics for evaluating managed  
16 pollinator protection plans.

17 The group had started back in October.  
18 We've been meeting monthly now. I can say I think the  
19 workgroup is working very well together. I think,  
20 again, they have a proposed approach, and I think  
21 we're looking forward to getting feedback from the  
22 committee and the workgroup on the approach and  
23 whether it's the right direction or if there are other  
24 factors that should be considered. So, there will be  
25 a presentation on that topic, you know, on the second

1 half of our segment here.

2 So, I'll start things off. So, the main  
3 topics, again we'll just talk about some of the  
4 activities, our commitments from the National  
5 Pollinator Health Strategy, we'll talk about managed  
6 pollinator protection plans, the acute mitigation  
7 policy, and then we'll finish up with the status of  
8 the neonic re-evaluation reviews.

9 So, as many of you probably already know,  
10 it's been about two years now that the federal  
11 agencies have put together a strategy. As part of  
12 that, the EPA had various commitments as far as that  
13 strategy in promoting pollinator health, namely  
14 looking at ways to better assess the effects of  
15 pesticides on pollinators. Also looking at expediting  
16 reviews on new products to help protect pollinators  
17 also. Also, pollinator habitat protection and  
18 development. But also in there there were commitments  
19 of looking at reducing potential exposures to  
20 pollinators from pesticide applications and also  
21 engaging states and tribes in developing pollinator  
22 protection plans.

23 Some of the recent activities that are  
24 ongoing, just notably, we're continuing to ask for  
25 pollinator data through data call-ins for our re-

1 evaluation program. Recently, I think it was earlier  
2 this year, the EPA hosted a workshop here in this  
3 building with stakeholders and looking at pollinator  
4 effects on non-Apis or non-honeybees.

5 As part of the ongoing efforts, we're still  
6 using the -- and this is an evolving science too, that  
7 we're using the pollinator risk assessment framework  
8 and looking at potential effects to pollinators from  
9 use of pesticides under our re-evaluation, and also  
10 our registration regulatory programs.

11 One area we're also taking a closer look at  
12 is the variability of the toxicity for residues on  
13 foliage study. This is the RT25 data. We'll be  
14 talking a little bit more about that later in the  
15 acute mitigation policy. But we're looking at finding  
16 ways to better utilize that data and to make it more  
17 specific for its intended uses.

18 So, managed pollinator protection plans, or  
19 MP3s, again, this is something the Agency had  
20 committed to in the very beginning. This was  
21 something that again was identified from some states  
22 that had taken this initiative earlier on in working  
23 with stakeholders in their states to develop  
24 pollinator protection plans. We thought it was a  
25 great idea and committed to working with states and

1 tribes to help other states and other areas, tribal  
2 areas, to also develop pollinator protection plans.

3 We hosted a symposium about a year ago here  
4 in Washington, D.C. for various stakeholders, states,  
5 tribal representatives, but also others to share  
6 experiences and lessons learned and provide  
7 information and tools for developing pollinator  
8 protection plans.

9 As you know, later last year, a workgroup  
10 was formed under the PPDC for providing  
11 recommendations to the Agency on how we can better  
12 evaluate or measure the effectiveness of these state  
13 plans more at a national scale, as opposed to just  
14 looking at each plan individually.

15 This was an area that I think -- again, we  
16 weren't sure what the best tools were for doing that,  
17 and we're really looking forward to the input for this  
18 workgroup and for the committee to give us some  
19 recommendations.

20 So, the acute mitigation policy, as many of  
21 you probably know, this is something I worked on.  
22 Again, it was a commitment coming out of the strategy  
23 that was released a couple years ago. The policy  
24 itself was finalized and released in January this  
25 year. We had a proposed policy, in which we received

1 a large number of comments that were considered. We  
2 made adjustments based on the comments. We thought  
3 the information we received was very informative.

4 In the changes that we made in the policy,  
5 it was more towards making the restrictions on the use  
6 of pesticides more quantitative, more risk based. So,  
7 based on the application rate and the toxicity of the  
8 compound, if a certain use pattern exceeded the level  
9 of concern, then we would impose restrictions on  
10 labels for products under certain conditions. That's  
11 in fields where pollinators are being brought in for  
12 commercial pollination services and the crop is in  
13 bloom. Those products will be restricted for use  
14 during those periods.

15 We also identified, based on the feedback we  
16 got from the comments, that there needed to be some  
17 flexibility about that overall restriction. So, we  
18 did look at areas where -- and we received quite a few  
19 comments on the reliance of, again, lower residual  
20 toxicity data out in the field, what we call RT25  
21 data. We thought that that was, you know, again,  
22 helpful information for growers, and it was being  
23 pretty widely utilized, from the feedback we received.  
24 So, we thought that was an opportunity to allow some  
25 flexibility for growers to use products when they



1       really needed it.

2               Also looking at some crops that are  
3       indeterminate bloom or long-term blooming periods,  
4       allowing for some flexibility use in products based on  
5       the potential impacts of just an overall restriction  
6       for any use of pesticide products.

7               Here is the basic language that we are  
8       looking to put on the labels that's included in the  
9       final policy document. I won't read the whole thing,  
10      but as indicated, for crops that require pollination  
11      services where bees are being brought in for  
12      pollination services and the crop is under bloom for a  
13      foliar application, we're looking at restricting the  
14      use of toxic compounds, toxic products that are listed  
15      within the policy document.

16              Under those conditions where -- again, the  
17      main words are here, foliar application of this  
18      product is prohibited to a crop from onset of  
19      flowering until flowering is complete when bees are  
20      under contract for pollination services. Again, we do  
21      allow some flexibility, and I'll talk about that here  
22      in a moment.

23              Again, depending on the application rate of  
24      those products and if they actually exceed the level  
25      of concern, again those products would be prohibited.

1     If they don't exceed our level of concern, again,  
2     based on the combination of toxicity and the  
3     application rate, those products will be allowed to be  
4     used under these conditions.

5             Again, as I mentioned earlier, there were a  
6     couple areas that we thought was appropriate to allow  
7     some flexibility around that overall prohibition.  
8     One, again, was reliance on lower residual toxicity  
9     compounds. So, if a product was identified what we're  
10    calling an RT25 of six hours or less, meaning that the  
11    toxicity of the compound basically reduces to a level  
12    that's acceptable within that six-hour period, these  
13    products can be used from two hours before sunset and  
14    up to eight hours before sunrise. So, basically, it's  
15    a nighttime application to allow for the toxicity to  
16    reduce to a lower acceptable level and allow for the  
17    pesticide products to dry before bees may be visiting  
18    the blooming field.

19            The other area, as I mentioned, was for  
20    longer term blooming crops or indeterminate blooming  
21    crops. Again, we received a lot of information on  
22    some of those crops that not allowing certain products  
23    would have a significant economic impact on the  
24    harvesting of those crops. So, we thought it was  
25    appropriate for those particular crops to allow

1 products under a nighttime application. Or, if the  
2 temperature is below 50 degrees, we recognize that  
3 bees generally aren't visiting the field during that  
4 time.

5 One other change that we made was regarding  
6 the environmental hazard statement. This was comments  
7 received from the state lead agencies. Some of the  
8 language that was included on some products in the  
9 environmental hazard section, which is more an  
10 advisory section, was too broad and was being too  
11 descriptive. It was creating potential confusion in  
12 the field and also difficulties in enforcement in the  
13 field as well.

14 Based on the feedback and recognizing that  
15 if states are having difficulty enforcing the  
16 language, it's probably not the best language to be  
17 having on the label. So, we did make some adjustments  
18 to the label, but keep in mind we are putting the  
19 language that I just mentioned earlier to be in the  
20 directions of use.

21 So, this language basically is again more  
22 advisory to letting the growers know that these  
23 compounds are potentially toxic and that they really  
24 need to follow the labeling and the directions for use  
25 to make sure to minimize exposure of the pesticide use

1 to pollinators.

2 So, with that, I'll turn it over to Yu-Ting,  
3 and she can talk about the latest on the neonics.

4 MS. GUILARAN: Good morning. How is  
5 everybody doing? Good? Excellent.

6 So, I just wanted to give you an update on  
7 where things are with the neonic re-evaluation. So,  
8 we're really talking about the four neonics,  
9 imidacloprid, clothianidin, thiamethoxam, and  
10 dinotefuran. So, as folks know, the pollinator only  
11 analysis was released January 2016. We received a lot  
12 of comments. I have been going through them. Just  
13 kind of going forward a little bit, we also released  
14 aquatic risk assessments associated with imidacloprid  
15 earlier this year, along with the two other neonics,  
16 clothianidin and thiamethoxam.

17 I know folks have been wondering where is  
18 that Federal Register notice. So, we're still working  
19 on that with our Office of Policy. As folks know,  
20 through transition, there are times that the new  
21 administration wants to take a look at what we have  
22 put out there. So, that is still in that process.

23 Yesterday, we had a really good discussion  
24 with Office of Policy. Hopefully, people will see the  
25 Federal Register notices soon. In the meantime, you

1 get a preview of what the draft risk assessment is all  
2 about and can start taking a look at our assessment  
3 and prepare your comments. So, we anticipate a 60-day  
4 comment period once we have the Federal Register  
5 notices out there.

6 Dinotefuran is the same position, which is  
7 along with all the other three neonics. A tier 1  
8 pollinator risk assessment has been posted and will be  
9 released for comment through the Federal Register  
10 notices as well.

11 So, what are we seeing from these  
12 preliminary risk assessments? We see some potential  
13 on-field risk for some use patterns. Some are low,  
14 really depending on how attractive the crops are and  
15 the different practices. The seed treatment uses tend to  
16 be low risk. Some potential on-field risk for some use  
17 pattern is still uncertain.

18 So, we're anticipating some more data coming  
19 in this year. Have some residue data coming in and  
20 also feeding studies. So, both are critical  
21 information for us to better understand through these  
22 tier 2 studies that is there really risk associated  
23 with these categories, the use pattern that's an  
24 uncertain category.

25 There are some on-field risks that we have

1 already seen with some use patterns. A couple of the  
2 ones that jump out, cotton and citrus, so I'll talk on  
3 the next slide a little bit about where we are with  
4 that.

5 Basically, our overall strategy on risk  
6 mitigation is really to engage the stakeholder as much  
7 as possible to really better inform us of not only the  
8 risk, give us feedback on the risk, but also the  
9 benefit of the chemical. So, as folks know, FIFRA is  
10 a risk benefit balancing statute, so we  
11 definitely need a lot of the information on the  
12 benefits to really kind of holistically look at that  
13 and also the risks associated with these pesticides.

14 So, there are a few things that are happening  
15 right now that we're reaching out to, specifically the  
16 citrus and cotton industries. So, we are talking to  
17 both Florida Fruits and Vegetables Association and  
18 also -- so, that's in May. And then we also have a  
19 crop tour that's coming up for California, which we  
20 will also talk to the citrus growers there. We also  
21 have something set up with the Cotton Council.

22 So, all of these are an effort to really  
23 understand some of the uses that are happening out  
24 there. So, we want to make sure that we understand  
25 the implementation and how things are being used, and

1       also the benefit of the different chemicals.

2               So, in general, this is kind of a summary of  
3       where things are and where we see that things will go.  
4       So, for the rest of 2017, first we'll have human  
5       health risk assessment for imidacloprid. And then, for  
6       the rest of the three, we'll have the preliminary  
7       pollinator assessments out there. Then we'll have the  
8       human health associated with those three as well. And  
9       then the other taxa other than the pollinators.

10              In 2018, our focus is really based on data  
11       that we receive in 2017 to update and revise as  
12       necessary and hopefully finalize these risk  
13       assessments. And with an eye towards 2018/2019, to  
14       have the different risk mitigation preliminary  
15       decisions, proposed decisions, out.

16              So, part of what we're contemplating too is  
17       usually our benefit assessment goes along with a  
18       proposed interim decision. For the neonics, it's  
19       probably a good idea -- and we've been working with  
20       our Biological and Economic Analysis Division -- to  
21       work on the benefit assessment for the different  
22       neonics. So, we will aim to also have that  
23       information available so people can provide us  
24       feedback so that we can take that into consideration  
25       as we're contemplating about the mitigation strategy.

1           MR. GOODIS: So, I think we're on track here  
2 right now. I think we have a few minutes to maybe  
3 take some questions on mine and Yu-Ting's talk before  
4 we ask the metrics workgroup to report out.

5           MR. KEIGWIN: So, let's start with Lori, and  
6 then Marc, and then I think that's Nichelle's card up.

7           MS. BURD: Thanks. So, you had proposed  
8 acute risk mitigation regulations, but instead issued  
9 a policy, which of course does not carry weight of  
10 law, and growers are free to ignore. Can you explain  
11 why you backed away from the regulations?

12          MR. GOODIS: Well, we didn't actually  
13 propose a regulation. I mean, it was a policy that  
14 was proposed initially. Again, this was a  
15 finalization of the policy.

16          We are intending on moving forward with  
17 letters to registrants for the products that were  
18 listed in the policy to start implementing, you know,  
19 the label language changes that I just described. You  
20 know, that's being finalized here within the program,  
21 and it still needs to go through senior management  
22 review before that can be released. I don't have  
23 exact timing on that.

24          I recognize there was some confusion about  
25 whether it was referred to as a regulation or not, but



1       it was strictly a policy, is what was proposed.

2               MS. BURD: Okay, just to be clear, the  
3       Federal Register described it as a regulation.

4               MR. KEIGWIN: So, I realize there was some  
5       confusion in the Federal Register. It got published  
6       in the regulation section, but it was clearly  
7       discussed in the notice announcing the availability of  
8       the draft policy, that it was a draft policy, and not  
9       a rule-making.

10              Okay, Marc, Nichelle, and then Wayne.

11              MR. LAME: Quick comment and then a question  
12       for clarification. My comment is very short. I  
13       really appreciate the rigorous work that the Agency  
14       scientists have put into this. So, good work.

15              So, it says on the last page on preliminary  
16       pollinator risk assessments that the Agency intends to  
17       engage stakeholders to inform itself. So, could you  
18       give me -- and I'd like to follow up with this, if  
19       possible -- name the stakeholders that you're talking  
20       about?

21              MS. GUILARAN: So, currently, we are looking  
22       at a preliminary risk assessment where certain uses  
23       are showing risk. So, I named two different grower  
24       groups. One is citrus, one is cotton. So, those are  
25       the ones that we have planned. But as always, we will

1 work with also our partner in USDA and also different -- we  
2 have different groups that come in and want to talk to  
3 us about neonics in general.

4 So, we are specifically right now going on  
5 these crop tours that were originally already planned  
6 or adding the citrus part to it so we can better  
7 understand how things are going in California and  
8 Florida in the citrus. Then we added recently a  
9 cotton tour as well. Does that answer your question?

10 MR. LAME: It does. I just want to make  
11 sure that actually, you know, beekeepers and consumers  
12 as well are represented in that list of stakeholders,  
13 or is that just kind of a if they show up kind of  
14 thing?

15 MS. GUILARAN: We have always had ongoing  
16 coordination with beekeepers. So, as always, if there  
17 are things that the beekeepers think that we should  
18 also make a side visit, we definitely will. We have  
19 in the past already done so, and we will continue to  
20 do that as well.

21 MR. LAME: Excellent. Consumers obviously  
22 are the end product of any risk here, you know,  
23 considering their food source. So, I hope that's at  
24 least part of it, although I know it is difficult.

25 MS. GUILARAN: Right. So, just to be clear,

1 we continue to have a transparent process that's  
2 associated with pesticide re-evaluation. So, anything  
3 that we determine or the benefit assessment on the  
4 different neonics and also the proposed interim  
5 decision, they're all for public comment. So, people  
6 obviously should take that opportunity as well.

7 We have to address every single comment as  
8 we're making our decision. So, that's another way for  
9 folks to provide input on how we're doing with our  
10 risk assessment, how we're doing with our proposed  
11 interim decision, and are we capturing the benefit  
12 correctly.

13 MR. KEIGWIN: Okay, Nichelle, then Wayne,  
14 then Cynthia.

15 MS. HARRIOTT: Hi. I have two questions.  
16 The first is your work on non-Apis bee exposures. You  
17 mentioned that EPA hosted a workshop recently. From  
18 that workshop, does EPA have a strategy for evaluating  
19 exposures to non-Apis bees?

20 Then, secondly, my other question is you got  
21 in your acute risk mitigation policy. On one of your  
22 slides, you're recommending the use of products with  
23 short residual toxicity times. I'm just wondering  
24 whether all the chemicals that you considered under  
25 this policy have RT25 data. If so, where can I find

1       that information?

2                   MS. ECHEVERRIA: Good morning. My name is  
3       Marietta Echeverria. I'm the director of the  
4       Environmental Fate and Effects Division. So,  
5       Nichelle, I'd like to respond to your question  
6       regarding strategy for non-Apis bees.

7                   Yes, it's correct. We held a workshop in  
8       January where we had academic scientists, government  
9       scientists, industry scientists, international  
10      scientists come together and work through the  
11      differences between exposure routes for honeybees  
12      relative to other non-Apis species.

13                  So, the next steps from that workshop are to  
14      do a comparison of exposure routes that our current  
15      process for honeybees may be missing and make an  
16      evaluation on whether or not the current process is  
17      sufficiently conservative to apply to those other non-  
18      Apis species. So, that's the first step going  
19      forward.

20                  On the effects side of things, we are  
21      continuing to work with OECD and other international  
22      partners on the development of toxicity testing for  
23      non-Apis bee species, including bumblebees. So, that's  
24      where we are with respect to the non-Apis issue.

25                  With respect to RT25 information, we do not

1 have RT25 information for all pesticide products. So,  
2 with the implementation of the policy, the RT25  
3 exception would only be applied to products that do  
4 contain those data that we've evaluated and we've  
5 found acceptable.

6 We do have a web site that lists the  
7 information that we currently have. We're working on  
8 a process to update that information annually.

9 MR. KEIGWIN: Okay, Wayne, then Cynthia,  
10 then Steven.

11 MR. BUHLER: I, too, want to echo Mark, and  
12 thank you for your work on this. I know decisions  
13 regarding pollinators are always tricky, challenging.

14 One aspect that I just have a quick question  
15 regarding, the acute risk mitigation policy affecting  
16 a crop under contract. Has there been consideration  
17 to like neighboring crops, knowing that bees forage  
18 two to five miles from the hive? How will that be  
19 addressed on the label?

20 MR. GOODIS: That's a good point. I mean,  
21 bees just don't stay in one particular area,  
22 obviously. But again, we're looking at those crops  
23 where they're under contract for service for  
24 pollination and those restrictions would apply. But  
25 that's the area where they're most likely to be and

1 the most likely to have exposure.

2 Any other applications beyond that scenario,  
3 we're relying on managed pollinator protection plans  
4 for beekeepers, and applicators, and land owners to  
5 have some sort of mechanism to communicate or  
6 coordinate the applications and minimizing national  
7 exposure of bees.

8 So, that was the general strategy, you know,  
9 that we had set up before. So, that's where we hope  
10 or expect that that type of interaction between the  
11 pesticides and the products would be addressed.

12 MR. BUHLER: Thank you.

13 MR. KEIGWIN: Okay, Cynthia, then Steven,  
14 then Sharon.

15 MS. PALMER: Hi. So, I have two questions.  
16 First, with the MP3s, to what extent will EPA guidance  
17 require that they include birds, butterflies, native  
18 bees, and other pollinators beyond managed bees?

19 Second, with regard to the pollinator risk  
20 assessments, I think it's great that you're focusing  
21 on the benefits, and you did some good work on  
22 soybeans before. I'm just wondering, for the seed  
23 treatment benefits, for which commodities we can  
24 expect a similar type of analysis?

25 MR. GOODIS: Well, I'll start on the first

1 question. Again, the managed pollinator protection  
2 plans are not mandatory; they're strictly voluntary.  
3 So, we are encouraging the development of these plans.  
4 Again, we're partnering with SFIREG and AAPCO and  
5 other organizations on the development. So, the whole  
6 concept is to allow the region, the state, or the  
7 tribe to identify what the particular issue is within  
8 their state or tribal area or region.

9           Based on the stakeholders that they are able  
10 to gather in that interaction, what are the real  
11 concerns in that particular area. What's the best way  
12 to address them and to make potential exposures? So,  
13 the states and tribes have the flexibility to expand  
14 beyond managed pollinators. I've seen where through  
15 revisions of plans, they've broadened the scope in  
16 some states to include habitat protection as well.

17           As far as other pollinators, again that's an  
18 option if they want to consider it. But again, this  
19 isn't something that's mandatory. So, it's really up  
20 to local stakeholders to identify what the priorities  
21 are.

22           MS. GUILARAN: Thank you, Cynthia. So, as I  
23 was mentioning before with FIFRA being a risk and benefit  
24 balance, I think we're going to start with the benefit of  
25 citrus and also cotton to accompany the risks that we have  
26 seen in some of the assessments.

1           MR. KEIGWIN: Okay, so, after these three, I  
2 think we're going to move on to the next part of the  
3 pollinator session. Then there will be some  
4 opportunity for additional questions at that point.

5           So, Steven, Sharon, and then we'll wrap up  
6 with Cheryl.

7           MR. COY: I took some notes here. You're  
8 looking at better ways to use RT25 data, so I applaud  
9 you with that. I think that will be very helpful.

10          The comment about, let's see, the bee  
11 analysis -- I get so nervous doing this. I don't know  
12 why.

13          So, I just would like to remind you that you  
14 need to incorporate the impact of moving colonies and  
15 the effects that the pesticides have on colonies in  
16 two months, six months down the road as opposed to  
17 just immediate impacts of a kill when the bee analysis  
18 is done to mitigate the risk.

19          And then, Mike, you mentioned that in the  
20 acute mitigation policy, acute risk mitigation policy,  
21 that -- initially, you said that the two hours before  
22 sunset -- the sun rises and nighttime application. I  
23 know several guys are cringing when I say nighttime  
24 application. Two hours before sunset is definitely



1 not nighttime. Then you mentioned the 50 degree  
2 temperature thing was maybe not accurate.

3 So, do you all have any plans on adjusting  
4 those times or temperatures on the label to reflect  
5 what your intent is?

6 MR. GOODIS: Right. Well, just to clarify,  
7 I mean, I wasn't perfectly clear when I was saying the  
8 two hours before sunset was mostly a nighttime  
9 application. I get it. You have a couple hours to  
10 allow for perhaps aerial application to take place,  
11 you know, before sunset. So, that was intended. So,  
12 you know, the timing that was proposed was what we  
13 intended.

14 Regarding the 50 degrees, we actually  
15 adjusted it from the proposed policy from 55 degrees.  
16 Based on information we received, the 55 degrees was  
17 too high. So, we actually lowered it. So, again,  
18 those are the intended restrictions for the policy.

19 MR. COY: Okay, thanks.

20 MR. KEIGWIN: Sharon and then Cheryl.

21 MS. SELVAGGIO: Hi. There's been some  
22 recent data that shows extremely high levels of  
23 residues of neonics in ornamental plants, both trees,  
24 shrubs, and flowers. I'm curious about the risk  
25 assessment process when you have a crop that

1 essentially moves off field but remains intact. In  
2 other words, you know, this is not a manual crop that  
3 the residues get incorporated into the soil.

4 Where does this fall in the risk assessment  
5 when you're considering that these residues remain in  
6 plant tissue and there's a potential for exposure off  
7 field?

8 MS. GUILARAN: So, we consider potential  
9 residues on field, and we would also do a  
10 consideration of any residues that we might expect off  
11 field. In terms of actual measured residue data, what  
12 we actually find, generally speaking, is that there's  
13 a refinement to our risk assessment process.

14 So, at the lower tiers, we're making very  
15 conservative assumptions about how much potentially  
16 could get into bee attractive matrices. Actually,  
17 when we have actual real world data that tends to actually  
18 refine our assumptions, it makes the risk assessment less  
19 conservative.

20 So, we will be considering monitoring data  
21 and other residue data that are available, both being  
22 generated by pesticide manufacturers and also those  
23 available in literature.

24 MR. KEIGWIN: Cheryl.

25 MS. CLEVELAND: That's a perfect lead in to

1 my question, which was citrus is a permanent crop, so  
2 it's right there. And cotton, as a row crop, is still  
3 highly regional. So, has there been any use of some  
4 geospatial incident reporting to help confirm or  
5 ameliorate the risk assessment? Likewise, has there  
6 been any use of any regional use laws for the  
7 pesticides that help? You said citrus and cotton are  
8 the things that have popped up.

9 So, has there been incident data from those  
10 regions or use logs of those chemicals to help  
11 ameliorate the risk assessments?

12 MS. ECHEVERRIA: So, in terms of utilizing  
13 incident data to confirm, we have characterized  
14 available incident data with respect to the risk  
15 characterization. In terms of actually having enough  
16 sufficient robust geospatial location information  
17 associated with those data, I don't believe those data  
18 are robust enough to make that kind of analysis. If  
19 we did have that data, we would be happy to  
20 incorporate that into the risk assessment.

21 With respect to refined usage information,  
22 we would consider that in the risk assessment.  
23 However, really, what chemical companies have agreed  
24 to do in response to our uncertainties around the  
25 pollinator risk is to develop a lot of residue data

1 following actual applications under field conditions.

2 So, those data are very useful for refining the risk  
3 assessment. That is part of the strategy.

4 When Yu-Ting was talking about that sort of  
5 middle tier crops where we have uncertainty, those  
6 data are designed to address those uncertainties.

7 MR. KEIGWIN: Okay, thanks, everyone. So, I  
8 think we're going to move into the second half of this  
9 discussion.

10 MR. GOODIS: So, we have Don Parker from the  
11 National Cotton Council as part of the metrics  
12 workgroup that graciously volunteered, right, Don?

13 MR. PARKER: Graciously volunteered is not  
14 what I would call it. I came to DC expecting to have our  
15 metrics workgroup meeting and not knowing that I was going  
16 to do this. But my distinguished colleague, Tom  
17 Van Arsdall, had an emergency fishing trip  
18 that came up. It's in D.C., we're all in D.C., so his  
19 secret is safe, I'm sure.

20 Anyway, the metrics group has made some  
21 pretty good headway, we think, on a very complex issue  
22 and a very challenging issue. It took us quite a  
23 while, though, to get our heads around what's actually  
24 the question that we're being asked. At first we  
25 caught ourselves asking questions about, okay, what

1       should be in an MP3, a pollinator protection plan.

2               Now, I want to say up front that whenever I  
3       talk about these today, I'm going to talk about an  
4       individual plan. You can call it a state plan, a  
5       tribe plan. Just for ease, I'm going to say  
6       individual plan a lot, but you know what I'm talking  
7       about now.

8               When we got ourselves caught into what are  
9       the questions that we need to ask, what's the  
10      components we need in this plan, then we realized  
11      that's not really what we were asked as a workgroup.  
12      That was not really the question that was put to us.

13              So, I want you to keep that in mind as we  
14      start moving forward because I want to very carefully  
15      lay out first to you -- because there are some nervous  
16      areas around what we're presenting. But I want you to  
17      very carefully look at what we're presenting as the  
18      entirety.

19              Whenever you think about the objectives that  
20      we brought forward, it's how to look at the state  
21      plans and come up with something that is a metric, is  
22      something that we can measure. It wasn't how to  
23      create a state plan. It wasn't what are the necessary  
24      components of a state plan. It was given these, how  
25      do you put some type of metric to it.

1           What we're asking the PPDC today is to look  
2   at what we're proposing and think about this as we get  
3   through this. Is this response from the workgroup  
4   meeting what you've asked us to do? If it is, do we  
5   continue in the development of this? That's the big  
6   focus for you to think through today in our proposal.

7           What we're proposing at this point is a  
8   point system. I know a point system makes a lot of  
9   people nervous, especially in individual states. But  
10   I want you to think about the entirety of this  
11   proposal. It's not a grading system; it is points,  
12   okay. There is no approval or disapproval. That's  
13   not what EPA said. It's not what they asked for.

14          They said is there something here that would  
15   help us give some kind of measurement, understanding,  
16   as to are these state plans making an impact, are they  
17   making a difference. And you're given the state plans  
18   already. And they are very diverse.

19          So, how do you look at that diversity, that  
20   complexity of cross different areas, and understand  
21   what is going on? The point system then gives credit  
22   where credit is due because it will add points for  
23   different areas, but it doesn't compare between  
24   states. It provides an individual plan measurement  
25   that can be monitored over time.

1           They start out with a certain number of  
2 points. They make some improvements. They have  
3 better points next year. It gives you a measurement  
4 over time. Then you can summarize those across the  
5 states to come up with a national metric that helps  
6 you realize on a national scale are we making an  
7 improvement.

8           With this type of system, it provides  
9 flexibility still for the local groups to focus in on  
10 what are the needs of their area. Whenever I show you  
11 some examples of what we're getting into here and you  
12 think about --

13           One of the big areas that we have here is  
14 participants. I think we all agree that the whole  
15 concept around these plans is can you get the right  
16 local stakeholders to the table. If they sit down at  
17 the table and they start talking to each other about  
18 this, they resolve a whole lot of it right there in  
19 that room.

20           So, one of the points would be the various  
21 stakeholder groups that you have engaged. Well, in  
22 California, that may be huge because you may have many  
23 different stakeholder groups. Whereas, in another  
24 state, there may be fewer crops grown there, fewer  
25 different stakeholder groups to have. So, there's

1 going to be variability. They're not comparable  
2 across states. They're comparable across time for  
3 that state.

4 It's also a mechanism that -- Katie gets  
5 nervous when I put this in there, but it's cheap, it's  
6 measurable, it's reportable, and it does not imply  
7 that EPA has approved or disapproved anything. So,  
8 keeping that in mind, and I will touch back on that  
9 again, but I want you to keep those in mind,  
10 especially it's not a grading system, it's not  
11 comparing between states.

12 Now, we looked at the complexity of  
13 everything we were given. We went through state  
14 plans. Believe me, if you get on the committee with  
15 Katie, volunteer to be the chairman. Do not let her  
16 be the chairman. She will load you down with work.

17 We looked at most everyone of the plans to  
18 try to see what are the commonalities, what's here,  
19 how do we start pulling this together. Then we  
20 identified some common categories that were in those.  
21 Then, that's when we started into this concept of this  
22 point system that looking at this national metrics and  
23 how would you implement some national metric, that we  
24 came up with some basic guides.

25 It's key to keep in mind that you were given



1     these diverse plans from the get go. So, whenever we  
2     started getting those common themes put together and  
3     putting them into different areas, we realized that  
4     each common category had multiple areas under that.  
5     You could kind of line those out for a point system  
6     measurement.

7             There are some other aspects that we've  
8     talked about. If we move forward, there's this thing  
9     called a rubric that once a point system could lead to  
10    how do you group some of this in a rubric. But right  
11    now we want you to focus on the point system.

12            As an example of one of those point system  
13    areas, we identified the participants. Like I said,  
14    if you think about who are the participants, there is  
15    still a lot of questions and all that you have to  
16    focus in on around that. Of course, we want all the  
17    producer groups there.

18            So, you get a point for each different  
19    producer group that's in this. You get a point for  
20    each different beekeeper group that's in this. You  
21    get a point for the state lead agency, the extension  
22    service, all of these different areas. The nice thing  
23    about it is are there some that we didn't think of?  
24    Fine. Add them to it. Give credit where credit is  
25    due. It provides the flexibility to show what that

1 state is really putting forth the effort to do.

2 Then, whenever you list all of this type of  
3 stuff out and you give these points, there are some  
4 areas that we were a little bit more sensitive about.  
5 What about federal agencies? We said give them a  
6 point one. No disrespect, Rick. The reason for that  
7 is very important. The local people have to own it.  
8 So, you can't give a lot of points to outside  
9 influence. The value is the local people have to own  
10 it.

11 So, this is one of the categories that we  
12 looked at. Then we identified communication where you  
13 could list out what are all the avenues of  
14 communication that are involved in this plan. Give  
15 points for all of those different avenues.

16 Education, what is your evidence that you  
17 have actually given this educational material into the  
18 hands of the participants around the country, around  
19 your state. That's a whole list of things you can  
20 have points for there.

21 BMPs, how many different BMPs do you have in  
22 your plan? You get point systems for all the  
23 different BMPs that may be added into your plan.

24 Progress measurements, so have you got some  
25 evidence that has shown that you have changed what has

1 happened in your state. Some states already have some  
2 questionnaires that they have developed. Those  
3 questionnaires have asked their participants are you  
4 more aware than you were the previous year? That's an  
5 evidence of change. Do you bring your stakeholders  
6 back to the table on an annual basis to improve your  
7 plan? That's an evidence of progress because you're  
8 keeping everybody engaged and involved.

9 So, that's back to the repeat of the slide I  
10 started you with, trying to keep this as tight and  
11 concise as I could to let you know where we are with  
12 this, this point system, but to make sure to emphasize  
13 it's not a grading system. It's a self-evaluation  
14 that you would provide to that individual planned  
15 leadership to tell them, okay, here are the things we  
16 need. Do you have the evidence of these areas? You  
17 would report a point back to EPA.

18 We would say that if we need to move forward  
19 with this, there would be a guidance document  
20 developed around this to explain what's the evidence,  
21 what's the different things, how do you lay all of  
22 this out.

23 We want to point out, too, to the group that  
24 this system, because of those lined items, it gives a  
25 guidance document of its own. Even though you're not

1 comparing between states, you all know how we all are.  
2 If we get numbers, we're worried about it, we've got a  
3 grade and who is beating us.

4 So, it gives some encouragement for others  
5 to look and say what did they get points for. Oh,  
6 here's something we hadn't thought about. We can add  
7 this to ours. So, it helps because it continues to  
8 expand and it's flexible. It helps guide continuous  
9 engagement and improvement.

10 So, that brings us just back to the closing  
11 of this plan being something that we would offer for  
12 the initial proposal to the group. We believe that  
13 EPA implementation of it, if recommended by the PPDC,  
14 would probably also maybe have a guiding committee  
15 over this aspect, the metrics, maybe in conjunction  
16 with USDA that would have a board to review what do we  
17 add, how do we change this as needed over time.

18 So, with that, I will turn it back to you.

19 MR. GOODIS: Thanks, Don. Stay here. So, I  
20 think we'll open up for questions. Now, there are  
21 actually other members of the workgroup that are on  
22 the panel here. If there's anything else that they  
23 would like to introduce or contribute to that  
24 discussion first?

25 (No verbal response.)

1                   MR. GOODIS: Okay, we'll open up for questions.

2                   MR. KEIGWIN: Okay, I see Tom, Marc, Liza.

3                   We'll start there. Tom?

4                   MR. DELANEY: One suggestion in those  
5                   different categories, that you might put a maximum  
6                   number next to some of those so it doesn't get so out  
7                   of balance. That might be a good thing to do.

8                   MR. PARKER: I think we've still got quite a  
9                   bit of work around where do you put the points? I  
10                  think that there is also value in how many points do  
11                  you give for participants versus did you develop some  
12                  brochure. Participants are probably more important.  
13                  So, I think there's still some discussion that we  
14                  have, but I appreciate that point.

15                  MR. KEIGWIN: Marc, then Liza, then Dawn.

16                  MR. LAME: You know, I find what you've  
17                  proposed very interesting. First of all, I want to  
18                  say, you know, continue in that direction regardless  
19                  of my comments.

20                  I will, of course, also say this is about  
21                  metrics. And we all know that if you can't measure  
22                  it, you can't manage it. So, the idea is that we do  
23                  want to manage it. On the other hand, if you don't  
24                  have a management plan in place, then measurements are  
25                  just numbers. So, we want to make sure that there's a

1     good situation there.

2                 First of all, I am always leery of self  
3     assessment. The idea of states doing points the way  
4     that you currently have it is an additive situation  
5     where you can just add on points, which I'm not  
6     entirely against. I think each group you get, add on  
7     points, for instance, which I like that.

8                 On the other hand, I think that there  
9     probably should be a subtractive element to this. So,  
10    if there are states where there are more incidents in  
11    a proportional sense, that maybe should be a minus  
12    point, just as a matter of metrics. You can have all  
13    the points you want, but it can still looked like hell  
14    when the thing is over with. So, I certainly would go  
15    with that.

16                Now, I know that's not the new American way.  
17    Everyone doesn't get a trophy that way, but I think  
18    it's probably a good management scheme.

19                I would always encourage the use of citizen  
20    scientists. There's lots of new research saying how  
21    productive citizen scientists are when it comes to  
22    this. They can be trained correctly and objectively.  
23    They would allow for a different dimension in  
24    measurement. So, that would be my suggestion. But  
25    good job.

1 MR. KEIGWIN: Liza, then Dawn, then Nina.

2 MS. FLEESON TROSSBACH: Thank you. I do  
3 understand that trying to determine from a national  
4 perspective if state plans are successful is  
5 challenging. I do have great concerns about this  
6 particular point system. This is a situation where  
7 the metrics were determined after states have  
8 developed their plans. The vast majority of plans are  
9 final or close to final. States were provided  
10 guidance, but it's a voluntary plan based on the local  
11 state.

12 So, we have our own measures that are  
13 specific to our states. To try to take those to a  
14 national level is problematic. The assumption that  
15 states are going to change their plan or continue to  
16 develop in a certain way to help inform this national  
17 success is problematic. It also puts into place, from  
18 what I understand, what's going to be required  
19 reporting for a voluntary plan that states did not  
20 have to do, and people do not have to participate in.  
21 So, I have concerns.

22 I also have concerns because we are human,  
23 and we do compare. No matter what anybody says, it  
24 will be a comparison between Virginia, who of course  
25 is going to have the most points, and somebody else

1     who is not. But that doesn't mean my plan is any  
2     better. So, I have really big concerns about this  
3     approach. Any type of -- while you say it's not a  
4     grading system, as soon as you put a number onto  
5     something, it's a grading system.

6             I do understand the concerns about self  
7     assessment. You know, if this was going to go  
8     forward, I'd rather have the EPA come in and assess  
9     the plan as opposed to putting that burden on the  
10    states. We've already done our work. We did the  
11    voluntary work. I believe states have a good plan  
12    based on their, you know, situation. They have  
13    metrics that I think they are happy to report.

14            But I do have concerns trying to put plans  
15    that were already developed into this system. This  
16    should have come first, the metrics, what the national  
17    success is and what state plans develop to be able to  
18    report the same type of information.

19            You have states that did not engage any  
20    stakeholders at the onset. They drafted a plan, sent  
21    it out. They have a plan that was acceptable to their  
22    state. You have other states who brought people in.  
23    So, you have so many different ways to do that.  
24    Grading based on that does not talk about how  
25    effective the plan is, and I don't believe that it



1 necessarily equates to the success of the plan for  
2 that state for the purposes.

3           You have states that are ag and non-ag. You  
4 have states that have crop-specific plans and those  
5 that have one. So, this system I don't believe lends  
6 itself to be able to truly access the success of these  
7 plans on a national level.

8           I mean, I think there's a way to do it, but  
9 at least preliminarily and based on what we've seen, I  
10 would say I can speak for state lead agencies that we  
11 would have grave concerns about this type of a system  
12 going into place. Thank you.

13           MR. KEIGWIN: Okay, Dawn, then Nina, then  
14 Steven.

15           MS. GOUGE: Thank you. My question is just  
16 for the whole group. As you reviewed the plans, were  
17 there any specific recommendations that you sent back  
18 to the people who submitted those MP3s? That's my  
19 first question.

20           I was very encouraged at the mention of  
21 mosquito abatement, particularly because we have some  
22 areas where day biting mosquitoes are going to be  
23 critically important vectors. If there's any  
24 additional information you can give us on that, I'd be  
25 keen to hear that. Thank you.

1           MR. PARKER: So, no, we did not send any  
2       recommendations back to the plans for the exact  
3       reason that she was mentioning there. It's hard to  
4       not slip back into the thought of are we trying to  
5       come up with a plan. No, we were not.

6           As we understand it, the question to the  
7       committee was, given these plans, how do we, without  
8       trying to change them, without involvement of them,  
9       they're not approved, they're not disapproved, we're  
10      not shaping the plans, given the plans, how can you  
11      put some type of metric together to get some idea of  
12      what they're accomplishing? So, with that, that's why  
13      we went that way.

14          The mosquito abatement or vector control  
15      type things are another group that had been identified  
16      by some states, not all, but some states had that in  
17      their plan. So, our whole approach on this was you  
18      don't have to check off each box, but give credit  
19      where credit is due. If this state went this  
20      direction, acknowledge that. If this state went a  
21      different direction, acknowledge that. It probably  
22      fit their local needs. But it gives you a way to see  
23      how they're progressing over time.

24          MR. KEIGWIN: Thanks.

25          Nina, then Steven, then Sharon.

1           MS. WILSON: Hi. So, I'm unclear when you  
2 talk about the metrics. Are the metrics bubbling up  
3 and you're looking for common metrics across the  
4 states that came from the plans that would be  
5 nationally accepted metrics and then have a corresponding point  
6 for a specific metric? I'm not sure I understand exactly how  
7 the point system works, beyond just the participation.

8           MR. PARKER: Okay. So, in this scenario, if  
9 you went through and gave a point for these various  
10 areas for that particular state plan or that plan, and  
11 then you sum that up, then you have a measurement for  
12 that state that year. The next year you do the same  
13 thing with their plan.

14          MS. WILSON: It's not common metrics; it's  
15 by state. They have their own stated metrics by  
16 state, okay. So, I understand the concern about the  
17 quantitative measurement not being exactly  
18 representative maybe of what's going on, but that  
19 doesn't discount that you could have a qualitative  
20 portion of that -- it doesn't have to be just all  
21 quantitative as well.

22          MR. KEIGWIN: Steven, then Sharon, then  
23 Richard.

24          MR. COY: Don, I know you're waiting on this

1 question. The purpose of the MP3 plans are to protect  
2 managed pollinators. The charges the EPA gave the  
3 workgroup is real close to impossible. I'm on the  
4 committee, but I just listened to a few of the  
5 conference calls. I mean, I think what you all have  
6 done is really good. It's beyond what I could have  
7 conceived it to come up with.

8 But the purpose of the plans are to protect  
9 the pollinators. There's no measurement of how  
10 pollinators are being protected in this point system.  
11 It's actually just measuring the plan. It's not  
12 measuring the objective of the plan, which is what I  
13 see as the point of this whole exercise.

14 So, any thoughts on how to measure the  
15 effectiveness of protection of the managed  
16 pollinators?

17 MR. PARKER: Sure. How much money do you  
18 want to put up? And that's what we wrestle with quite  
19 a bit. You know, we had a lot of discussions about  
20 different things, but with the recognition of they're  
21 all costly. The committee was trying to do its best  
22 not to try to put any unfunded burden back on the  
23 states.

24 Now, obviously, yes, there's a little bit of  
25 answering some points that may be put back on the

1 state, or it's possible EPA could do it themselves.  
2 But they'd have to ask states to submit the evidence  
3 and all. To say that it's not measuring anything, you  
4 would essentially be saying that you do not believe  
5 the goals of the state plans have anything to do with  
6 pollinator protection. I believe that the goals of  
7 the state plans do have a lot to do with pollinator  
8 protection.

9 I believe whenever you get those  
10 stakeholders to the table and they sit down across  
11 from each other and start working out commonalities,  
12 that that is a very strong change in pollinator  
13 protection right there. Does it measure pesticide  
14 residue? No. Does it measure the level of varroa  
15 mite? No. But it measures a cooperative group that  
16 is working together to try to mitigate risk.

17 MR. KEIGWIN: Sharon, then Richard, then, in  
18 the interest of time, we'll just see if there are any  
19 PPDC members on the phone who want to speak. Then  
20 we'll conclude this session. So, Sharon?

21 MS. SELVAGGIO: I think this is a really  
22 intriguing framework that you've come up with. I have  
23 a few different thoughts and questions. First of all,  
24 there are people that kind of specialize in  
25 evaluation. I'm wondering if you had anybody like

1     that on your committee, because evaluation is sort of  
2     its own science.

3             So, just to kind of build off Steve's  
4     comments about implementation monitoring -- in other  
5     words, have you basically monitored the plan versus  
6     monitored the outcome? I think that that's an  
7     important point and something that if you ran this  
8     framework by people who are skilled in evaluation, you  
9     might be able to get some good feedback. So, that's  
10    one comment.

11            When you talk about locally driven, I think  
12    there's a lot of strength in that. I would suggest  
13    that maybe there might be baseline measures that  
14    should be assigned points separately from add-ons that  
15    might be suggested by local stakeholders. So, if a  
16    set of baseline measures that is considered important  
17    enough that you would want every state to try to  
18    achieve full points on that, just because of the point  
19    tendency that we would have to sort of assign points  
20    for whatever and have this grading system, it could  
21    become meaningless. So, I think that there's a need  
22    for certain baseline measures independent of whatever  
23    local stakeholders would add on.

24            I guess my last point is that we didn't  
25    really see enough on the detail from what you

1 presented, especially on the progress measurements.  
2 That's the most critical piece because, again to go  
3 back to Steve's point, if you are giving people  
4 information, knowledge is power, but people may not  
5 implement best management practices no matter how many  
6 times they hear them. This is a voluntary effort. It  
7 relies not only the information but on people's  
8 willingness to implement and actual implementation of  
9 those measures.

10 So, I would suggest that you have within  
11 your progress piece of this an ability to measure  
12 people who have received the information, have they  
13 actually implemented it. I think you need monitoring  
14 on behalf of the pesticide applicators or the farmers.  
15 Have they implemented these practices, these best  
16 management practices, to really understand if in  
17 addition to whatever objective measures you might  
18 collect on bee health and so on and so forth, to have  
19 some idea of whether people are actually taking this  
20 information and putting it to use.

21 MR. PARKER: We had that discussion as well.  
22 We did have some evaluation experts to come in and  
23 talk. We talked about the complications around these  
24 measurements. A lot of times it still goes back to  
25 what is the question.

1           The question we were asked was, without  
2   interfering with these voluntary plans, how would you  
3   create a metric. That's very hard whenever you're  
4   wanting to talk about okay, let's mandate a monitoring  
5   on this. Well, it's a voluntary plan. You can't  
6   mandate a monitoring on it.

7           So, given what is here, can you put some  
8   type of indices here that gives us an idea over time  
9   that it's doing something. I mean, the committee has  
10  gone from starting to think about what exactly needs  
11  to be in the state plan to what's the questions that  
12  we need to ask of a state plan.

13          Then it all kind of turned around and said  
14  we're looking from the bottom up. We're not supposed  
15  to be starting at the state plan building process. We  
16  need to be looking from the top down saying given this  
17  set of cards, how do you make sense of what's going  
18  on.

19          This was our proposal that we've come up  
20  with at this point for the committee. Yes, there's  
21  still a lot of work to do on details. We do have a  
22  list. The committee decided that maybe under each of  
23  those categories, that long list was a little bit too  
24  much on a slide for everybody to digest in this time,  
25  because our question mainly to you as a committee is,



1 do we move forward with this? Is this the direction  
2 that meets what you're asking the workgroup to do? Do  
3 we move forward with this to develop that other and to  
4 develop the guidance around what those areas are, or  
5 do we need to find a different avenue?

6 MR. KEIGWIN: Richard?

7 MR. GRAGG: Okay, I'm a little confused on  
8 this whole objective here. You said that you were  
9 asked to come up with your approach without  
10 interfering with the plan, right? So, then, to me --  
11 and if you're looking top down, then, then you, in my  
12 opinion -- one approach is to measure or assess  
13 whether or not the plans are being implemented or  
14 operationalized. That's a yes or a no. Then there's  
15 a degree of implementation.

16 Then, the other, from a top down, in my  
17 opinion, is whether or not the plan is achieving what  
18 they said they were going to achieve. If you're not  
19 going to interfere, you're not going to go into the  
20 weeds, then, to me, I think your numbers or your  
21 metrics or your rubrics should be around those two  
22 things.

23 Then one way in terms of a national approach  
24 is to assess the plans and group them in terms of  
25 maybe some similarities. Then you may have different

1 pools. Then you could group those together in some  
2 type of assessment outcome or indication.

3 But I do think as well that you should work  
4 with the states to get them to collaborate with each  
5 other in terms of improving the plans based on EPA's  
6 analysis or assessment or review. I do think it's  
7 very important on the evaluator.

8 I think looking back, in an ideal situation,  
9 you would have an evaluator help the states put  
10 together the plan. The whole thing the evaluator is  
11 putting into the plan is helping them set it up to  
12 accomplish their objectives. So now going back, maybe  
13 an evaluator could help them improve that, get those  
14 things in there. That would be a benefit to the  
15 state. It's not a burden. You would be lending some  
16 level of assistance, so I think it would be received  
17 well.

18 MR. KEIGWIN: Let me just check and see if  
19 there are any PPDC members who wanted to speak on this  
20 topic who are participating over the phone.

21 MR. HANKS: Rick, this is Doug Hanks.

22 MR. KEIGWIN: Go ahead, Doug.

23 MR. HANKS: In the past four years, this  
24 pollinator issue has been on the table. It seems like  
25 it's been in my estimation pretty well discussed and

1     gone through. The original four metrics that we  
2     talked about, if you look at the plan, the fifth  
3     metric that I'd only suggest, is the awareness now  
4     from 100 percent to 1,000 percent. That ought to be  
5     included in these metrics of these plans as we've  
6     discussed today. That's all I wanted to mention.

7             MR. KEIGWIN: Thanks.

8             Any other PPDC members on the phone who  
9     wanted to speak?

10            MARK: This is Mark with Apiary Inspectors  
11     of America. I just wanted to throw out there --

12            MR. KEIGWIN: I'm sorry, you can participate  
13     or make a comment on this during the public comment  
14     session at the end. Right now, this is only for the  
15     members of the PPDC.

16            I think Dawn had one more comment to make,  
17     and then we'll conclude this session.

18            MS. GOUGE: Thank you. I just wanted to  
19     back up the comments -- but I would ignore that. I  
20     really think that this is a lost opportunity for  
21     anybody to go through all of these plans and review  
22     them and then not give feedback to those people. I'm  
23     even okay with the self-assessment part because I feel  
24     that the teams that are looking for opportunities for  
25     improvement will take any feedback that you give and

1 work on it.

2 They're voluntary, so nobody is mandated to  
3 do anything. I think you're in a position of great  
4 strength. Feedback that would be given would be at  
5 the discretion of the groups involved to put those  
6 practices. But to go through that process --

7 I also wanted to ask if that's an evaluation  
8 or review that's going to happen annually, or even if  
9 the team comes together annually. Getting some  
10 feedback now would be something that they may choose  
11 to implement over five year plans or however long.  
12 Thank you.

13 MR. KEIGWIN: Mike, anything to wrap up?

14 MR. PARKER: No, I don't think so. Is the  
15 consensus of the committee that the workgroup should  
16 move forward based on that the feedback received in  
17 general? Is the approach and the scope of the efforts  
18 meeting its initial goal? Again, the goal is to  
19 provide a final recommendation to the committee in  
20 November. I think the group will be on track to do  
21 that if this is the right direction. So, violent  
22 objections?

23 MS. FLEESON TROSSBACH: I do have grave  
24 concerns about the point system. I understand what  
25 EPA is trying to do. I understand the purpose. I've

1     been involved with this since the very first time it  
2     was mentioned about pollinator protection plans. All  
3     state lead agencies have, AAPCO has, SFIREG has, and  
4     we've expressed our concerns.

5             I do believe that there is a way to measure  
6     the success on a national basis. I think it needs to  
7     be based on the state plan. The way they developed  
8     the plans, we were given latitude to develop them as  
9     we saw fit, measure them how we saw fit for our state,  
10    for our industries, for anywhere there's crops, for  
11    our apiary industry. I think a point-based system  
12    just is not going to really give you that particular  
13    measure.

14            I think that I would personally like to see  
15    the workgroup go back to the table and not necessarily  
16    get rid of the idea behind the point system, but I  
17    agree with my colleague here from Florida A&M that the  
18    plans are already in place.

19            Virginia has worked on our plan for 18  
20    months, and it's now final. We've done a lot of work  
21    on our plan because we were given that latitude to  
22    make it our own. We're open to comments, et cetera,  
23    but we were given the ability to develop our plan  
24    based on our program. We have our own metrics. If  
25    you want to look at our metrics and somehow maybe

1 group categorize, communication was a big focus on  
2 this, do that.

3 So, I think it can be done. But, once  
4 again, I have concerns about the point system, and  
5 those particular items that were pulled out, and how  
6 that data is going to be used. Our plans have never  
7 been evaluated by anybody else except our own  
8 stakeholders and our agencies.

9 The EPA indicated straight up that they're  
10 not going to approve them, they're not going to review  
11 them. But yet, we're going to be measured based on  
12 our plans and our components for our plans, when all  
13 we were given was guidance and latitude.

14 So, once again, I just have grave concerns  
15 about that approach. I do believe there's a way to  
16 measure it, but I think additional work and other  
17 considerations need to be taken into play or into  
18 consideration.

19 MR. KEIGWIN: So, what I'm hearing, noting  
20 Liza's remarks, is that the workgroup should continue  
21 doing work mindful of the point that Liza and Richard  
22 were also making, that these plans are in place. So,  
23 sort of a retroactive development of metrics could be  
24 challenging, but the workgroup should continue working  
25 and let's see where you all are come November. Does

1       that work?

2               MR. PARKER: All right.

3               MR. KEIGWIN: All right, so that was a great  
4       discussion. The downside is we're 15 minutes behind  
5       already after the first topic. But I think we can  
6       make up some time. So, why don't we come back here at  
7       11:00. That clock is only a few minutes fast, so keep  
8       that in mind.

9                               (Whereupon, a brief recess  
10                              was taken.)

11              MR. KEIGWIN: So, our next session is  
12       Preparing for Future Products of Biotechnology. So,  
13       let me turn things over to Bob McNally, and he's got a  
14       crew that's going to work us through this session.

15              MR. MCNALLY: Yes, thanks, Rick. I just  
16       wanted to say that when we discussed ag biotech with  
17       you all last fall, we covered two areas, if you might  
18       recall, from that session. There was a White House  
19       memo issued in 2015, and it sort of outlined three  
20       things that the federal government needed to do. The  
21       first was the coordinated framework update. That was  
22       to clarify the current roles for EPA, FDA, and USDA.  
23       As we talked about in the fall, that was issued in  
24       September 2016. That's just updating the roles, or  
25       clarifying the roles, in the coordinated framework.

1 We had a presentation by Mike Mendelsohn on  
2 that.

3 The second piece of that memo was to outline  
4 a long term strategy for ag biotech. That also was  
5 issued in September 2015. My sense from that meeting,  
6 you all had a lot of interest in this area, so we're  
7 sort of back here for a sequel.

8 We did not cover the third item then because  
9 it had not yet been issued, and that's the item you  
10 see here. It's the NAS report on ag biotech. That  
11 was issued in January. That's available online if  
12 you'd like to get a copy of that.

13 What we want to do today, though, is provide  
14 an overview of that report's key information as it  
15 relates to your mission here with PPDC. There's other  
16 information there you might find interesting about how  
17 the federal government should improve its training,  
18 should improve its risk assessment processes.

19 But we want to focus in on what you were  
20 interested in last fall, which is what are these  
21 technologies, and how might they have pesticidal  
22 applications that are of interest to you, and when  
23 might they arrive here at EPA, and, more importantly,  
24 what do they mean to you in terms of who you represent  
25 here at the table.



1           So, the feedback, we have questions in the  
2 back of the presentation that we need from you. It  
3 includes these novel technologies, might they address  
4 some of the issues that are important to you. If so,  
5 how? The second question is, do you have concerns  
6 with these technologies. If so, what are those  
7 concerns? And then, what other stakeholders need to  
8 be involved in this discussion?

9           Now, as I said last fall, in a few years,  
10 rather than the topics you see on today's agenda, we  
11 might have new ones that are very, very specific to  
12 these technologies. So, sort of in the movie  
13 nomenclature, Chris Wozniak's presentation this  
14 morning is kind of like the coming attractions that  
15 you see when you go to the movie theater. However, we  
16 think in the very near future, some of these  
17 technologies and their registrations may become sort  
18 of the feature presentation.

19           So, today we want to give you an overview of  
20 some of those and get feedback. So, with that, let me  
21 introduce our sort of leading man to go over this  
22 morning's coming attractions. Chris has been  
23 following sort of the horizon scanning with these  
24 technologies for a number of years and has a lot of  
25 expertise in these areas.

1           So, with that, let me turn it over to Chris  
2           for this morning's presentation.

3           MR. WOZNIAK: Thanks, Bob. I've never been  
4           introduced as a sequel or a coming attraction or a  
5           leading man, but I think that's a positive thing. Get  
6           your popcorn, and we'll get started.

7           So, as Bob mentioned, this is like the third  
8           prong of this effort where we had the CF update, long-  
9           term strategy, and then the NAS, or National Academy  
10          of Science, engineering medicine report came out a few  
11          months ago.

12          By the way, I apologize. I meant to put the  
13          URL on here. I can send it today. I can send it  
14          around to you. There's a PDF of this available online  
15          for free, so you can download all 200 pages of it.  
16          It's a thick, meaty document. So, my emphasis when I  
17          say brief summary is on "brief". We're going to focus  
18          on one particular area.

19          So, this slide here, the first one, is one  
20          that I borrowed from Richard Murray, the panel chair  
21          of that committee. Again, this commission of an  
22          external independent analysis of the future landscape,  
23          basically an attempt to be as clairvoyant as possible  
24          and looking 5 to 10 years out.

25          Again, a rather meaty report, so there are

1 several areas here, all very interesting. My focus is  
2 going to be really on number 4, on understanding risk  
3 related to future biotech products. Quite frankly,  
4 what are some of those biotech products.

5 For some of them, the future is already here  
6 knocking on the door. Other ones, again we have to  
7 extrapolate and speculate a little bit. But yet,  
8 given the way the technologies are moving forward so  
9 rapidly, it's certainly within the realm of  
10 possibilities without any hyperbole needed.

11 So, statement of task, the panel had several  
12 areas that they were to address. Some of my  
13 colleagues would say there were some things that they  
14 weren't supposed to address, but they still did. So,  
15 I think we definitely got our money's worth in that  
16 respect.

17 Again, I'd like to focus here on the  
18 potential for these future products and whether they  
19 pose different risks. Are they somehow different than  
20 the regulatory system as we know it today and our risk  
21 assessment processes won't be able to handle it?  
22 That's the simplest way to put it.

23 So, we're going to look into some of those  
24 specific products and talk a little bit about the  
25 potential challenges that they will give to the

1 agencies. I also want to point out that regulation is  
2 not static. We're constantly horizon scanning, but  
3 also improving our techniques for risk assessment or  
4 just trying to further our understanding of possible  
5 exposures in the environment to all kinds of biotech  
6 products from microbials of all different kinds to  
7 plants and even mosquitoes.

8 So, here's a partial list of some of these  
9 novel products. On the right side I put a time frame.  
10 This is, in some cases, I think, pretty accurate, in  
11 some cases it's my guesstimate or my speculation.  
12 I'll point where that is the case.

13 So, these male-sterile genetically  
14 engineered *Aedes aegypti*, or yellow fever mosquitoes,  
15 for population suppression, they're obviously a  
16 reality. You've certainly seen them in the news  
17 lately. They're in review at FDA currently, and I'll  
18 talk a little bit more about that in detail a few  
19 slides later.

20 The Wolbachia-based mosquito population  
21 suppression mechanisms, those are already in house and  
22 being reviewed. Again, I'll go into more detail in a  
23 minute.

24 Gene drives, that's a really interesting  
25 area, I think. This is for both plants and animals.

1 This could be for something agricultural like pest  
2 control, pest management. It could also be for  
3 conservation. There's a group that's working, for  
4 example, on rat and mouse control on Pacific islands.  
5 I'll go into a little more detail later as to how this  
6 might work.

7           There's currently a moratorium on use of  
8 these gene drives, so again, we're looking probably at  
9 5, maybe even 10 years out, before they're a  
10 reality in the environment. However, in laboratories  
11 and in discussions and meetings, these are already  
12 here and being discussed thoroughly.

13           I'll talk a little bit about the American  
14 chestnut and the efforts to engineer that for blight  
15 resistance, one of my favorite projects. That is  
16 also, shall we say, knocking on the door.

17           The microbial consortia is something that the  
18 panel paid some attention to. Some of these may be  
19 more TSCA oriented. They may be more for soil  
20 remediation. They might be for geomining. But some  
21 of them could have pesticidal properties.

22           The reason that this is significant is that  
23 it's quite likely these microbial consortia will have  
24 novel genetics. They may have synthetic sequences,  
25 even synthetic non-natural nucleotides. They could

1 certainly have kill switches, most likely will to  
2 prevent their spread and persistence in the  
3 environment. So, there's a whole area there.

4           Again, I applaud the panel for focusing in  
5 on that, because, as I said, I was impressed when I  
6 saw the presentations on geomining and people using  
7 bacteria to concentrate metals and things. This is  
8 exciting stuff.

9           Synthetic double stranded RNA for RNA  
10 interference, inhibiting gene expression, again,  
11 already here. There will be nuances, changes to it,  
12 certainly. Some products we haven't seen that we know  
13 are out there by talking to academic and industry  
14 researchers. Some are already, like I said, in house  
15 in review.

16           These genetically recoded organisms, this is  
17 again a case where you're literally changing the  
18 genetic code so that organisms that you release may  
19 not be able to talk to each other. In other words,  
20 they can't exchange DNA because they're using two  
21 different sets of score cards to express genes. So,  
22 these are all things again, maybe a few years down the  
23 road, but certainly within the realm of possibility  
24 soon.

25           And gene edited plants, microbes, animals,

1 we've seen a lot of that in the news, certainly.

2 These could be small tweaks to the DNA sequence that  
3 can have major ramifications. In some cases, they're  
4 knocking out a gene. In some cases, they're turning  
5 on a gene. In some cases, they're modifying the  
6 protein that's produced by that gene, et cetera.

7 So, there's a whole gamut there. We have  
8 not seen these come through the door yet. Other  
9 regulatory agencies have, however. I have no doubt  
10 that it's just a matter of time before one is  
11 submitted to EPA.

12 So, I'll talk a little bit initially about the  
13 two mosquito products that I mentioned. Again, the  
14 emphasis here is on population suppression. The  
15 first, the *Wolbachia pipientis*, this is a bacterium  
16 that lives symbiotically within the cells of certain  
17 insects, really about a million species. Some people  
18 estimate about 60 percent of all arthropods have  
19 *Wolbachia* of one type or another in them, also in some  
20 crustaceans, some nematodes as well.

21 The beauty of this system is that you end  
22 up, if you have mischaracterized strains -- in other  
23 words, the male and female have different strains or  
24 one is missing a bacterium completely -- you end up  
25 with non-viable eggs. Therefore, the population goes

1 down over time.

2 The second is the genetically-engineered or  
3 oxy type mosquito that I mentioned in the previous  
4 slide. Again, this is already in field testing in  
5 other countries and on the verge here. It's being  
6 reviewed currently at FDA.

7 Both of the technologies work through a  
8 release of just male mosquitoes. I want to emphasize  
9 that. So, these mosquitoes aren't the kind that can  
10 bite people. Secondly, they're incapable of  
11 reproducing. They're short lived, so they don't  
12 persist in the environment.

13 So, first we'll talk about the OX513A  
14 mosquito from Oxitec. This is one that I think is  
15 really a nifty system where in the laboratory you have  
16 the larvae in your little pan of water. You keep  
17 tetracycline in there and that keeps them happy and  
18 they're able to reproduce. Once you remove the  
19 tetracycline, they'll die. So, that's a bit of an  
20 oversimplification, glossing over some molecular  
21 biology, but for the sake of brevity, they require the  
22 tetracycline to complete their life cycle.

23 There's also a red fluorescent marker  
24 protein in there that can be used to track these in  
25 the environment. So, when you release the males and



1 they're carrying this DS red protein, they mate with  
2 the native females, and you can see it in the  
3 offspring. The interesting thing about this one is  
4 the larvae go through their first few molts and  
5 actually compete with other larvae in their little  
6 puddle of water. It's significant from a competition  
7 standpoint. Then they die before they would pupate  
8 and go on to become adults.

9           Again here, population is the stated goal.  
10 It's not about saying this will eliminate Zika or  
11 change the disease incidents. That certainly could  
12 happen. But the claim is for population suppression,  
13 and that's one of the reasons that EPA has pending  
14 oversight over these mosquitoes.

15           As I mentioned, outside of the country there  
16 is credible efficacy data in several instances and  
17 ongoing studies in several countries. Both of these  
18 products require repeated release. The amount and how  
19 often you do it will depend on the situation. Early  
20 in the season when the populations are high, you're  
21 going to be releasing more mosquitoes because you want  
22 about six or seven times as many males as there are  
23 native males that are going to compete for the  
24 females. So, you do your baseline measurements, your  
25 range finding before and then you do your releases.

1       These only last a couple days in the environment.

2               So, you release them twice a week, maybe in  
3       some cases even three times a week. You're constantly  
4       monitoring to see what's happened to the population.  
5       And over the course of a few months, you would see  
6       that population go down in some cases, the published  
7       studies, 92, 94, 96 percent. So, that's pretty  
8       significant.

9               So, I mentioned FDA having current  
10       oversight. To kind of put it in a nutshell, currently  
11       there is a guidance document that was published online  
12       for comment. The comments were received. We're  
13       waiting for that document to be signed off on over at  
14       FDA and the Center for Veterinary Medicine.

15              Following that, those mosquitoes that are  
16       indicated for population suppression will come to EPA  
17       for oversight. Those that are making claims of say  
18       reducing viral titers in the mosquitoes or reducing  
19       the number of virus particles or the incidence of a  
20       disease, that's an animal drug. So, that would remain  
21       with the Center for Veterinary Medicine as an  
22       investigative new animal drug.

23              So, on the Wolbachia, I mentioned it's a  
24       bacterium. However, it's one bacterium that you just  
25       can't culture in a petri dish the way you can with so

1 many others. That has frustrated a little bit of the  
2 research, although it made some great headway in  
3 understanding the mechanism quite recently.

4 As I said, about 60 percent of all insect  
5 species, depending on who you ask, are presumed to  
6 have this. There are some mosquitoes, for example  
7 *Aedes aegypti*, that typically don't. There's one  
8 report of one incident of having a natural *Wolbachia*,  
9 but, in general, they don't.

10 That's significant because again, as I  
11 mentioned, if you release the males with a *Wolbachia*  
12 strain and the native population of females don't have  
13 a *Wolbachia*, then you end up with these non-viable  
14 eggs. The eggs are laid. You've occupied the  
15 female's time for mating, but it's a dead end.

16 So, again, you're looking at population  
17 suppression over time with releases, again, occurring  
18 depending on the density of the area, the number of  
19 houses in the area. You might be trying to  
20 (inaudible) this mosquito in, the population of the  
21 mosquitoes themselves, et cetera.

22 So, again, the releases, take them with a  
23 grain of salt, once, twice a week, maybe even three  
24 times a week. Again, monitoring with ova traps for  
25 eggs and adult traps to see where the population is

1 going as you progress through the season with multiple  
2 releases.

3           You know, with both of these technologies, I  
4 mean, they are only limited by how many production  
5 facilities you want to build, basically, and produce.  
6 You can produce millions of mosquitoes a week in a  
7 relatively small facility. Again, depending on the  
8 density of area where you're trying to treat, you can  
9 treat whole neighborhoods, even small cities.

10           Some of this has gone essentially commercial  
11 in Brazil, for example, with the Oxitec mosquito. If  
12 you're interested, again there's a great little film  
13 on line about five minutes and it shows you how they  
14 do it. It's rather impressive.

15           So, the regulatory status, if I didn't  
16 mention it earlier, this is a microbial biopesticide  
17 because we're dealing with a bacterium. There have  
18 been some field trials in California, in Kentucky,  
19 upstate New York. There are a couple pending here,  
20 some that actually have just started releasing in  
21 Florida and also in certain parts of California.  
22 There's also a pending registration for Aedes  
23 albopictus, the Asian tiger mosquito, that will likely  
24 be completed this year as well.

25           So, I mention these products because they're

1 on the cusp. I mean, they're right here ready to go.  
2 There's already been some field testing. So, we will  
3 see how that turns out, how the data looks.

4 In terms of gene drives, again, this one is  
5 a little bit further in the future, as I mentioned,  
6 simply because I think, appropriately, the scientific  
7 community has said this is a very powerful tool. We  
8 really need to think about what we're doing, and we  
9 need to get input not just from the scientific  
10 community but from a broader cross section of society.

11 The way this works is simply to skew the  
12 inheritance of a specific gene. So, for example, we  
13 typically have paired chromosomes. We have 23 pairs  
14 in our body. You've got roughly a 50/50 chance of  
15 getting the genes from one or the other into the sperm  
16 cell or an egg cell. With the gene drive phenomenon,  
17 you can get essentially 100 percent.

18 So, if you want to drive that gene into the  
19 population, every single offspring is going to contain  
20 your gene. So, that's extremely powerful. You can  
21 see, if you put in a gene that deleterious to an  
22 organism, you could, in theory, drive that organism to  
23 extinction. So, that's a different scenario than what  
24 we're used to dealing with.

25 Functions in sexually reproducing organisms,

1     if your organism clonally propagates like some  
2     plants do, it's not going to work. It's not going to  
3     work in bacteria or viruses. Won't work in long-lived  
4     elephants, humans, other things, whales. It's not  
5     going to function there. But for a lot of other  
6     things, you can see some annual weeds perhaps could be  
7     the target of a gene drive, mosquitoes, rats, and  
8     mice, as I mentioned on Pacific islands.

9             So, again, the National Academies has done a  
10    great job with the report. There's the URL for those  
11    of you who are interested. Again, a thick document,  
12    good bedtime reading. But it's very interesting  
13    stuff, and there are meetings going on, I can tell  
14    you, all the time around the world, people focusing on  
15    what can we do with these gene drives and what should  
16    we be really considering ahead of time before we get  
17    to that point of environmental release.

18            Island conservation dot org has a good  
19    website. Again, I urge you, if you're interested in  
20    more detail, they have some published peer review  
21    articles, as well as press releases on there. I don't  
22    think I need to tell you just how devastating some of  
23    these rodents have been on certain islands, I mean,  
24    just wiping out bird species as well as changing the  
25    flora as well. They really ruined some areas.

1 Dropping broad spectrum toxic pesticides has helped  
2 to some degree, but it also obviously has its  
3 consequences and costs. So, this would be a really  
4 powerful technique.

5 I should also mention some of these, and one  
6 of the ones that they're considering, is a naturally  
7 occurring gene drive. They still have to do some  
8 genetic engineering, but it's not like the  
9 CRISPR/Cas9s you may have heard of; it's a naturally  
10 occurring gene drive in this mouse where only males  
11 are produced. With a world full of male mice, what  
12 can I say. But anyway, it's a dead end for the  
13 population.

14 The great thing is, starting this off on an  
15 island kind of makes sense because whether it's a  
16 mosquito or a mouse, if there's some level of  
17 containment simply by the geographic isolation of the  
18 island, I think some people would be a little bit more  
19 interested in it.

20 Another example, avian malaria carried by  
21 mosquitoes, wiping out honey creeper species on  
22 Pacific islands. That's another area where folks,  
23 both government and academic and private, are looking  
24 at potential for attacking that mosquito on these  
25 islands, driving it to extinction at least locally,

1 and hopefully saving the honey creeper species from  
2 extinction.

3 RNA interference with pest control already  
4 here, but there are some nuances that we haven't seen  
5 yet but we likely will see. So, these can be  
6 expressed in plants. We have that already under  
7 review. It's actually been registered for a seed  
8 increase for corn root worm control.

9 But here's an example where this is a group  
10 at Beltsville that's highlighted in the URL at the  
11 bottom, the UMD EDU news. They're looking at brown  
12 marmorated stinkbugs and gypsy moths and targeting  
13 again specific genes that you can silence. So, you  
14 pick a gene that's specific to that organism. You get  
15 the sequence just right, and you make sure that that  
16 gene is important enough that the organism either dies  
17 immediately or can't reproduce or whatever, but just  
18 simply leads to population suppression.

19 Now, some of these can be even as a spray.  
20 I mentioned it can be expressed in plants. You could  
21 express them in bacteria. You could put out live  
22 bacteria with these or you could heat kill the  
23 bacterium and use them just as a carrier and a  
24 production model for your double strand RNA. You  
25 could put your double strand RNA into a bait, whether



1     it's for ants, fire ants or something like that, or  
2     whatever, and have it target them. It doesn't work in  
3     all species the same. Certain lepidopteran  
4     (phonetic), for whatever reason we don't fully  
5     understand, it doesn't seem to be as functional, but  
6     it certainly has great potential.

7             So, I should just mention these can also be  
8     used to reverse herbicide resistance and weeds. So,  
9     you can target the gene that's giving the resistance  
10    and potentially, at least theoretically, tank mix it  
11    with the herbicide and undo the resistance and kill it  
12    at the same time.

13            Gene editing for plant disease resistance,  
14    we have not seen this come in, as I mentioned earlier.  
15    Other agencies like APHIS have seen these types of  
16    products come through their door. We will soon. I  
17    have absolutely no doubt.

18            So, I'll just give you one example of the  
19    power of this technique. This doesn't have to but  
20    often uses CRISPR/Cas9 for gene editing. TALENs are  
21    another method or another product that can be used to  
22    edit the gene sequence at a fine level.

23            So, this one is bread wheat. Bread wheat  
24    isn't simple the way I mentioned, where we all have  
25    paired chromosomes. Well, they have three sets of

1 pairs. So, when you try to breed this conventionally,  
2 it's like the whack-a-mole. You do something here and  
3 something else pops up. It's very difficult, if not  
4 impossible, just to breed in this resistance for this  
5 fungus that causes a powdery mildew.

6 With this system, these folks were able to  
7 change all copies. There's really three sets times  
8 two, so it's six alleles, or six genes, and edited in  
9 one fell swoop. Basically, what they did, I  
10 mentioned, there's 530 DNA base pairs changed. It  
11 sounds like a lot, but if you consider the size of the  
12 genome and the billions of (inaudible), it's  
13 minuscule.

14 These are gene knockouts, so there's no new  
15 protein produced. No potential for allergenicity  
16 alterations, other than what wheat already has. If  
17 you look at the picture on the lower right, you can  
18 see on the far right that leaf surface is clean. The  
19 others all have the little white spots, the mildew on  
20 them. There's a big reduction, obviously.

21 In fungicide use, if you don't have the  
22 fungus, you don't have to spray. This can be a very  
23 devastating disease in terms of yield loss. But, in  
24 addition, it's a timing thing and you have to play  
25 games and predict. Well, I think it's going to be a

1 bad year; I'm going to go ahead and spray. So, your  
2 fungicides may or may not hit the target, may or may  
3 not be needed, but you sometimes can't wait to put  
4 them on. So, the reduction here is significant.

5 There's an interesting article there on PBS  
6 dot org that I mentioned below, if you're curious  
7 again. It's called Editing Out Pesticides. So, these  
8 can be really powerful tools for reducing all kinds of  
9 pesticides, not just fungicides.

10 American Chestnut Research and Restoration  
11 Project, as I mentioned, is one of my favorite topics.  
12 I think it requires big thinking and a brave heart, so  
13 to speak. This is totally out of the normal paradigm  
14 of OPP in the sense that at least with biotech, we  
15 tend to look at highly managed row crops and things,  
16 cotton, corn, potatoes, et cetera, some public health  
17 pest control.

18 This is about engineering a tree and putting  
19 it out into the environment all over the place. This  
20 map is the historic range map of the American  
21 chestnut. You can see from Maine to Mississippi,  
22 quite extensive, obviously a dominant tree in the  
23 eastern forest at one point. Thanks to this fungus,  
24 there are just stumps with sprouts for the most part  
25 left. There are a few isolated populations of trees

1       in Wisconsin and up in the northeast.

2               But basically, without genetic engineering,  
3       the breeding efforts with the Chinese and European  
4       chestnuts, it helped some, but you don't necessarily  
5       get an American chestnut habit. The form is not the  
6       same, and you don't get the degree of resistance that  
7       the Chinese trees already have.

8               So, coupling that breeding scheme with this  
9       genetic engineering I think will be a successful  
10      route. Bill Powell, who is at the State University of  
11      New York in Syracuse, is headlining this effort but by  
12      no means works alone. There are state chapters all  
13      over the eastern seaboard that deal with the American  
14      Chestnut Foundation and academic institutions that are  
15      trying to move this forward.

16              The nice thing about it is it's a fairly  
17      simple system. They took an oxalate oxidase gene from  
18      wheat, put it in there. Oxalate is critical for this  
19      fungus to do its damage. You knock out the oxalate,  
20      you don't get the damage. It doesn't mean the fungus  
21      can't maybe hang on and grow there for a bit, but it  
22      does not cause the big cankers and the damage that  
23      really are the death now of this tree.

24              As I mentioned, the ultimate goal is to put  
25      it out there. It raises questions like, well, who

owns it, is this going to be -- as Bill and I have talked, this is going one of those grandiose projects where by the time it's successful, everybody that worked on it is going to be dead. That's the simple truth. So, you have to have some foresight.

As I said, I have a brave heart and realize that all this effort, you'll never know if it really worked. But we do have some preliminary data from APHIS field permit that these trees are looking good and they'll continue to be bred with other American chestnuts that the foundation has identified.

So, APHIS would regulate this because there are plant pest sequences involved and the genetic engineering of the chestnut. Of course, we would look at it because it's a pesticidal mode of action for that transgene. FDA would probably look at in a voluntary sense. It's not clear since they look at allergenicity issues whether the use of a wheat gene might raise some issues with them. That's all still yet to be decided.

But we have had several meetings with this group, the three agencies, and certainly we think that the safe exposure to this oxalate oxidase gene, which is present in all kinds of grains but also a lot of dicot or vegetable species, things we eat pretty much

1 every day. So, there's no reason to think that the  
2 oxidase enzyme is a health issue.

3 So, general predictions, I mentioned they're  
4 trying to look out 5 to 10 years. But one thing  
5 that's clear, more complexity for sure, just the  
6 diversity of the types of organisms, but also the  
7 techniques used to create those organisms. This idea  
8 of sort of having A, C, D, and G for your nucleotides  
9 and your DNA and adding in a new one changes the  
10 language, literally, for the DNA. That's something  
11 new.

12 Having synthetic sequences where you replace  
13 the whole chromosome in a fungus, chromosomes that  
14 have never been seen before in a natural environment.  
15 Those are going to present challenges to the risk  
16 assessment. Certainly, there would be a lot more  
17 likelihood, I think, of probabilistic quantitative  
18 risk assessment and also based on modeling to try and  
19 understand this. I'm not sure some of the experiments  
20 could be done in a typical manner the way we do with  
21 acute tox studies, for example.

22 Also, the diversity, obviously pesticides,  
23 that's our interest. But these will run the gamut, I  
24 mean all kinds of products. There's some of them I  
25 wish I could tell you about I've been talking to. The

1 companies, of course, are very silent on what they  
2 want to do with some of these newer products. I mean,  
3 they touch your lives in all kinds of ways, not just  
4 on the pesticide side of things.

5 They also caution that the number of  
6 products coming in could really increase and that, as  
7 Bob mentioned, they suggested probably more training  
8 and, quite frankly, even possibly just more people to  
9 deal with these in the sense that if there aren't  
10 adequate people to deal with the risk assessments and  
11 the regulatory and legal matters, that it's always  
12 possible you'll hold up progress. So, that's a  
13 consideration from the panel.

14 So, the conclusions, as I said, this is very  
15 lengthy. I apologize for just taking one slice of  
16 this report. There's a lot more in there. Certainly,  
17 as I said, if you crack the cover on that file, you'll  
18 see what I'm talking about.

19 I think I've covered most of this already,  
20 so I won't say much more about it. We continue to  
21 look over the report, even though we've read it  
22 several times. Over time, the types of products we  
23 see will no doubt cause us to go back and reflect on  
24 what's been said in that report, and even the one  
25 before that, the one that I guess came out in 2015.

1 Fred Gould ran that panel on products of biotechnology  
2 as well.

3 So, we actually do stay in touch with some  
4 of the panelists and have a back and forth, almost a  
5 debate, about certain topics. So, this is a living  
6 document, so to speak.

7 So, with that, I guess we get back to the  
8 feedback area. We certainly would appreciate your  
9 input. Bob already went over some of these points, so  
10 I won't reiterate them, but we're certainly open to  
11 questions.

12 MR. MCNALLY: Maybe just to start, if you  
13 have any clarifying questions for Chris on the  
14 technologies, then, if you want, we can turn to the  
15 questions on the last page here to go through and get  
16 feedback and advice from you all. But any just  
17 general questions about the technologies that Chris  
18 could perhaps clarify?

19 MS. PALMER: Thank you. That was a  
20 tremendous presentation, really interesting. So, I  
21 appreciate your putting it together. I think that in  
22 particular the mosquito control technologies have real  
23 potential for human health. They may also have  
24 potential in the Hawaiian islands, the bird extinction  
25 capital of the world. We are very interested in those



1 technologies for the control of avian malaria.

2           So, I wanted to ask, it seems like the  
3 regulation of the Wolbachia is fairly straightforward  
4 as a microbial pesticide. But my first question is,  
5 with the Oxitec genetically-engineered male mosquitoes,  
6 you said that FDA has those now and the ones for  
7 suppression go to EPA. I'm wondering, once they get  
8 to EPA, what is the process and what can we expect  
9 when they get to EPA?

10           My second question is with regard to the  
11 gene drives. We do have more concerns, obviously,  
12 about those and potential global consequences. I'm  
13 just wondering is there some sort of international  
14 regulation or treaty or something underway so that we  
15 don't have to worry about what might happen in all the  
16 different countries developing those gene drives?

17           MR. MCNALLY: Thanks Cynthia. Let me handle  
18 the first question. Maybe Chris and I can do a tag  
19 team on the second.

20           I think your first question is what happens  
21 when it's sort of given to us in terms of the transfer  
22 from FDA. Basically, the company, just like the  
23 Wolbachia group, could pursue an EUP with us. There  
24 are possibilities for a Section 18 with us.  
25 Obviously, the reason you do a Section 5 and EUP would

1 be to perhaps get additional data that would support a  
2 Section 3 registration.

3 One thing we've committed to do in the  
4 previous administration is that for any of these novel  
5 technologies, we feel it's important to have an  
6 independent peer review with our science advisory  
7 panel. So, I can't prognosticate the future, but  
8 that's how we've handled things in the past with BTs  
9 and with RNAI. I think that would be something we  
10 would do in a similar fashion. So, to answer your  
11 question, the company could pursue a Section 5, a  
12 Section 18, and ultimately a Section 3 registration  
13 with us.

14 On the second question -- are you aware of  
15 anything in terms of internationally, Chris?

16 MR. WOZNIAK: I'm not aware of anything  
17 specifically intended to address gene drives. I would  
18 think, to some degree, the Cartagena Protocol on  
19 biodiversity and transfer, what they refer to as LMOs,  
20 cross country lines, might have applicability in some  
21 cases. But that's obvious concern, as I mentioned,  
22 that you can potentially cause an organism to go to  
23 extinction. Once it's released, how do you stop it  
24 from crossing a border.

25 There are considerations already underway

1     where people talk about various technical fixes, so to  
2     speak, remediation plans, that have to be in place  
3     before you even consider a release so that you can  
4     call something back. There are even some cases where  
5     people talk about protecting relatives of the species  
6     with a sequence beforehand so that if a gene drive  
7     somehow got into it, it would have no effect.

8             So, all of these are under consideration,  
9     but I'm not aware of a specific legal remedy yet.

10            MR. MCNALLY: Just a quick point from the  
11     report that we couldn't cover, I think there was a  
12     recommendation that we need to include, the social  
13     sciences. There are ethical issues here. That's  
14     something that was made fairly strongly when you're  
15     talking about gene drive and what that might mean.  
16     So, that's also another finding/recommendation from  
17     the report.

18            MR. WOZNIAK: One other thing I'll mention  
19     just briefly with regard to your first question is  
20     that a couple of us did work with FDA and CDC on the  
21     environmental assessment review when the Oxitec  
22     mosquito came into FDA over the last year and a half,  
23     roughly, two years. So, we have that experience  
24     jointly with those other agencies. FIFRA is obviously  
25     a little different than the Food, Drug, and Cosmetic

1 Act, for example, or the National Environmental Policy  
2 Act. So, what we look at in OPP may be slightly  
3 different, but the biology is the same.

4 MS. CLEVELAND: So, I guess I would like to  
5 follow up on Cynthia's call for international  
6 engagement. It looks to me like you're trying to  
7 still figure out what the US government is going to do  
8 and the different agencies. I get that. But as these  
9 are emerging technologies, the system will emerge all  
10 over the place. You already quoted several other  
11 countries.

12 So, I would have thought, and I'm not  
13 familiar with the report, that there should be  
14 something very strong in there about getting  
15 international engagement. I know EPA is always  
16 resource constrained. I get that. But boy, is this  
17 one very, very important to be at the table as the  
18 other governments around the world start to make their  
19 risk assessment policies, or regulations, or laws, or  
20 whatever.

21 So, there must be some format for  
22 international discussions on these as they emerge.  
23 It's very important for our government to be there at  
24 the table.

25 MR. MCNALLY: Agreed.

1 MR. KEIGWIN: Steven, then Gabrielle, then  
2 Nichelle.

3 MR. COY: Pretty basic question. With  
4 regards to the RNAi and -- I don't see where I was  
5 looking for that triggered my note, but there's a new  
6 biofungicide that the almond industry is using this  
7 year. So, with those type of things, are you looking  
8 at the effects on honeybees for those with the whole  
9 neonicotinoid thing?

10 After X number of years, now we're looking  
11 and going back and saying, hey, maybe we should look  
12 closer and a little more deeper. I just want to make  
13 sure that you don't forget those things could affect  
14 honeybees or all pollinators.

15 MR. MCNALLY: Yes. I guess as a general  
16 point, obviously, no matter what it is, we have the  
17 same sort of data requirements that people have to  
18 satisfy. So, the bee issue would be something that we  
19 in the biopesticides program look at currently and  
20 will look at in the future with all these novel  
21 technologies.

22 MR. KEIGWIN: Gabrielle and then Nichelle.

23 MS. LUDWIG: I'm moving away from just  
24 questions. Is that okay? So, one, I just want to say  
25 thank you for following up on some of the comments

1 from the last PPDC, basically saying you only looked  
2 at where we were, not where we're going. So, this has  
3 been very, very helpful to see how much thinking has  
4 been going on, particularly because of the NAS report,  
5 but reflected within the Agency. So, just thank you.

6 A couple things that I think -- I don't know  
7 where this belongs, but I second Cheryl's point that  
8 nothing we do sticks just in the United States  
9 anymore. So, how do we deal with that?

10 I think the other thing, and this comes up a  
11 lot, is really understanding the tradeoffs. Whether  
12 you're talking about the citrus and bee issue or  
13 talking about soil fumigants, talking about varroa  
14 mite control, these technologies could really be game  
15 changers in terms of pesticide use. So, being able to  
16 understand, okay, sticking with what I'll call a  
17 traditional technology versus these new technologies,  
18 what are the new risks, old risks? I think for OPP in  
19 particular, that's going to be a question that will  
20 come up a fair bit. How does this compare to what  
21 we've been doing in terms of --

22 I mean, this is not my personal opinion, but  
23 the more I've worked on pesticides, the more I've come  
24 to the conclusion that if we can make the plant  
25 resistance, the better off we are, because the way my

1 analogy is, it's like medicine but you take a shower  
2 in the medicine. When have you ever taken a shower  
3 and not a drop of water has not gone where you didn't  
4 want it to go? So, that's our issue with pesticides.  
5 So, if we can make it internal, that would be very  
6 powerful.

7           Again, our tradeoff -- and I do think OPP is  
8 going to have to struggle with how do we quantify  
9 that? That's again something new in this whole arena,  
10 because you're going to have people who are utterly  
11 against it for their reasons. People are going to be  
12 totally for it for their reasons. Really being able  
13 to understand what are the societal benefits and costs  
14 in terms of traditional pesticide use.

15           MR. MCNALLY: Thanks, Gabrielle. A quick  
16 point on that, just on the mosquitoes, one of the nice  
17 things about this technology is that those darned male  
18 mosquitoes find a way to find the female mosquitoes no  
19 matter where they are.

20           Now, if you're spraying a conventional  
21 pesticide, you're spraying where you think the  
22 mosquitoes are. So, there's actually, potentially,  
23 some additional benefits that some of these  
24 technologies have. Some of the points you made, but  
25 also in terms -- and we'll have to see the data over a

1 longer term, the success rate in terms of addressing  
2 the issue.

3 MR. WOZNIAK: Let me just add. I think one  
4 of the things that, I apologize, I should have made  
5 clear is that I think with all the technologies that I  
6 discussed, without exception, there's a higher degree  
7 of specificity involved. I mean, I think that's one  
8 of the key criteria for making these so valuable.  
9 That's, in many cases, defined by either RNA or DNA  
10 sequence.

11 But, in addition, we do always examine  
12 persistence, whether it's a chemical pesticide, a  
13 protein, RNA, whatever. So, that's the other side of  
14 the coin. Like with these RNAs, we already have some  
15 quantitative data on how long they tend to last in the  
16 environment. Compared to some of the synthetic  
17 chemicals, it's much, much shorter.

18 MS. LUDWIG: Just one other addition.  
19 Again, our other encouragement is for some of these  
20 conversations to be taking place with our research  
21 agencies. I have experienced about four years ago  
22 talking to both NIFA and ARS, and they were touting  
23 RNAi technologies like it's going to solve all of  
24 our pest management problems. I mean, I'm not  
25 kidding. That's pretty much what both of them said.



1           I, knowing the regulatory side, immediately  
2   said, okay, what's the regulatory status. They looked  
3   at me blankly. I'm going, okay, you're saying this is  
4   where our research should go, but you haven't stepped  
5   back and said where are we in the regulatory world.

6           So, my other plea is find ways, especially  
7   as these new technologies move forward, to have some  
8   conversations about what do you need on the research  
9   end to help you make good decisions. I think that  
10   would be helpful.

11           Again, similar to what Cheryl is saying, can  
12   we avoid some of the problems we've seen if we can  
13   have some dialogue in advance with the research  
14   community.

15           MR. MCNALLY: Chris can follow up on this in more  
16   detail, but it's as if you've read the report. That's  
17   one of the findings, to have better -- are you like a  
18   plant that Chris talked to you before to tee these  
19   things up? But yes, that's important. I think one of  
20   the things that Chris has done a great job in the four  
21   years I've been in this division is that we've had  
22   several meetings with the research entities.

23           We try to engage them, because they are sort  
24   of -- even the fellow research agencies are clueless  
25   about how to go down this path. So, one of the things

1 we want to do is to continue doing that but do a  
2 better job and have more proactive outreach to them  
3 rather than waiting for them to come.

4 Chris, I don't know if you have any from  
5 your own experience.

6 MR. WOZNIAK: Well, certainly. I used to  
7 work for ARS and I worked for the progenitor of NIFA,  
8 CSRE, years ago. As a matter of fact, I used to  
9 direct the biotech risk assessment grants program  
10 there, which we still participate in. So, that  
11 program is ARS money largely for a service to answer  
12 the questions regulators have. So, we have FDA,  
13 APHIS, and EPA there at the grant review for the  
14 proposals.

15 But, in addition, we also help write the  
16 request for applications to make sure that our  
17 questions are getting addressed. It is a competitive  
18 environment, so not everything we want necessarily  
19 gets funded. It's a small pot of money, but it is  
20 significant for us.

21 MR. KEIGWIN: Nichelle.

22 MS. HARRIOTT: I just have a quick general  
23 question about the mosquitoes and how this all works  
24 for the Wolbachia and the GE mosquito. These focus on  
25 the male mosquitoes. So, my question is, and this is

1 just a clarifying question for my education, how many  
2 females will these mosquitoes mate with, and how far do  
3 they fly to find these females in terms of that  
4 general efficacy of the technology?

5 MR. WOZNIAK: Well, the mosquito, now  
6 specifically with *Aedes aegypti*, but it's true of  
7 actually several other mosquitoes that vector viruses  
8 -- you're looking at a fairly small range. I mean,  
9 the maximum they probably would move, absent the  
10 tornado or hurricane, is about 200 meters. But, in  
11 most cases, it's actually significantly less than  
12 that.

13 So, when they're releasing, and I didn't  
14 point it out on that slide, but you can see somebody  
15 that looks like they're flying a large flute, they're  
16 blowing through a tube full of mosquitoes to blow them  
17 up into the air. Sometimes they do it out of the side  
18 of a van window with like a cylinder full of male  
19 mosquitoes. So, they'll go off and mate.

20 I don't know specifically how many times  
21 they can mate. There are some mosquitoes that will  
22 mate once after a blood meal and then move on. But  
23 there's just some really interesting work on  
24 frequencies of wing beats that control the attraction  
25 between the mosquitoes.

1           Some people are actually using this now as a  
2 possible way to disrupt this. There are mosquitoes  
3 that will mate multiple times, and some that are  
4 highly specific to a particular frequency mate once  
5 and go off. So, I don't know that I can answer your  
6 question simply.

7           MR. MCNALLY: We have about eight or nine  
8 minutes left. We can go through each of these  
9 questions. But if you just want to look at all those  
10 that we have on the chart, or any ones in particular,  
11 we want to make sure we hear from you today. If we  
12 run out of time, don't hesitate to contact us directly  
13 in BPPD. We'd love to chat with you more about these  
14 technologies, what they might mean to you.

15           But any other feedback on these questions  
16 from members of the PPDC?

17           MR. KEIGWIN: Richard.

18           MR. GRAGG: The second question on new  
19 concerns, I'm sure you're already doing it. But I  
20 think the public is probably one of those audiences  
21 that we want to help understand risk and the benefits,  
22 what this new technology is, because I think there's a  
23 lot of times people don't get the right information.

24           MR. KEIGWIN: Robyn.

25           MS. GILDEN: Obviously, being a nurse,

1 healthcare providers, nurses, doctors, various other  
2 public health officials need to be in the conversation  
3 on the health effects end.

4 MR. WOZNIAK: Any others? Oh, question down  
5 there.

6 UNIDENTIFIED FEMALE: I'm just curious, what  
7 is being done in terms of the health effects end?  
8 There's a lot of research in terms of -- we've heard a  
9 lot about how well these work and how well they can  
10 control mosquitoes. But what are the plans when we  
11 introduce these new technologies to be able to monitor  
12 the potential human health impacts of this technology?

13 MR. WOZNIAK: Well, what I can tell you is  
14 it depends on whether you're talking about Wolbachia  
15 or you're talking about Oxitec. They're somewhat  
16 different. I'll start with Wolbachia.

17 Wolbachia, as I mentioned, is in over a  
18 million species. There's no doubt that you have  
19 consumed it and will continue to consume it whether  
20 you are eating lettuce from the salad bar or fresh  
21 veggies from your garden or whatever. Wolbachia is in  
22 nematodes, all kinds of other arthropods. So, there's  
23 a very long history of safe use with that bacterium.  
24 There's no evidence for any sort of infectious nature,  
25 at least with mammals, or vertebrates, for that

1 matter.

2 As far as the Oxitec mosquito goes, again,  
3 the only differences are there's the red fluorescent  
4 protein I mentioned as a marker. That analysis has  
5 actually already been done 10 or 12 years ago by FDA.  
6 There's a document online. If you're interested, I  
7 can send you that. Looking at things like homology to  
8 allergens, homology to toxins, digestibility in a  
9 monogastric mammalian stomach. So, those are the  
10 kinds of examinations. I don't remember if there was  
11 an acute oral toxin of that particular state or not.  
12 With the other protein, the tetracycline responsive  
13 activation protein, it's a bacterial protein, an  
14 original derivation, would likely already be in your  
15 gut if you have E. coli as a resident of your  
16 microflora.

17 So, again, history of safe use, there's no  
18 known homology with any toxins or allergens. Again,  
19 unless you're riding a motorcycle without a helmet on,  
20 your chances of consuming these mosquitoes is probably  
21 pretty low. You could get an occasional one, but I  
22 think the exposure side is significant.

23 That's one of the beauties of both the  
24 systems, as Bob alluded to. Number one, they can get  
25 into places that we can't with a spray boom. But, in

1 addition, they're male species looking for a female of  
2 a specific species.

3 When we look at some of the conventional  
4 chemicals for mosquito control, one of the first  
5 questions is, we've got to test three or four species  
6 of mosquito. There's no point in doing that with  
7 this. They are pretty specific. The *Aedes aegypti*  
8 don't want to mate with *Culex pipiens*. So, the  
9 specificity I think is one of the strongest points of  
10 that. It's hard to fathom a way that they would be  
11 injurious to humans.

12 MR. MCNALLY: Just a quick follow up, we had  
13 the same data requirements for microbials for this  
14 stuff as we do for the other ones we deal with. So,  
15 the non-target populations that might consume the  
16 mosquitoes we'd be looking at as well for both of these  
17 types of technologies.

18 So, basically, we still follow the same  
19 process we do for anything else that comes before us  
20 to make sure it's safe for humans and also safe for  
21 the environment.

22 MR. WOZNIAK: As I recall, I think there was  
23 a fish study involved with the original environmental  
24 assessment as well. The predatory mosquitoes are  
25 actually mosquitoes that predate on other mosquito

1     larvae in aquatic situations. Those kinds of tox  
2     studies were run without effect.

3             MR. KEIGWIN: Well, thanks, everybody. So,  
4     we are about to break. We have four sessions this  
5     afternoon. A couple of them are pretty quick. So,  
6     let's try to be back in the room for 1:15. Thanks.

7                     (Whereupon, a luncheon recess  
8                     was taken.)

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## 1 AFTERNOON SESSION

2 MR. KEIGWIN: Session 3, we've only planned  
3 for 30 minutes, so Anna and Garland will lead us  
4 through the presentation for about 15 minutes, and  
5 then we'll have about 15 minutes for questions.

6 Garland, are you leading us through this?  
7 Okay, I'll turn things over to you.

8 MS. WALEKO: I'm Garland Waleko. I'm a CRM  
9 in the Pesticide Re-evaluation Division. I co-  
10 coordinate the modernization efforts for the acute tox  
11 6-pack with Anna Lowit. I'm going to talk about that.

12 For folks who don't know, the acute tox 6-  
13 pack studies are required for all new AIs and all  
14 formulation for purposes of precautionary labeling.  
15 So, the hazard category, the signal word, re-entry  
16 intervals, things like that. There's three acute  
17 studies, the oral, dermal, and inhalation, and then  
18 the eye irritation, dermal irritation, and dermal  
19 sensitization. So, those are the six studies we'll be  
20 talking about.

21 So, by way of a little bit of background,  
22 OPP developed a strategic direction for new pesticide  
23 testing and assessment approaches in response to the  
24 2007 National Academy report on toxicology testing in  
25 the 21st century. This is about adopting integrated

1 approaches to testing assessment. AIATA is the  
2 acronym.

3 This is a hypothesis based, systematic  
4 approach to integrated exposure and hazard in  
5 assessing risk. So, it's more of a weight of evidence  
6 approach. The goal is to use a broader suite of  
7 alternatives, so computer-aided methods, also known as  
8 in silico, to better predict potential hazards in order  
9 to focus testing if testing is necessary, improving  
10 approaches in the current tox test to reduce use of  
11 animals, while also expanding the amount of  
12 information that we get, as well as understanding tox  
13 pathways better so that we can develop those  
14 alternatives.

15 Also, in response to the 2007 NAS report,  
16 OPP came up with guiding principles for data needs for  
17 pesticides. This is for EPA staff. The purpose was  
18 to provide consistency in identifying data needs while  
19 promoting the use of knowledge that we already have,  
20 and focusing on what data we really need to do risk  
21 assessment and make those decisions. The purpose is  
22 to increase efficiency and move away from a check-the-  
23 box kind of approach.

24 The purpose of this slide is to show that  
25 there is flexibility in implementing Part 158 data

1 requirements. For example, we can waive data. We can  
2 ask for more data than is specified in the CFR. So,  
3 there is room to accept alternatives.

4           These are the 6-pack studies that I  
5 mentioned. This shows how many we get per year from  
6 2012 to 2015. So, you can see that's quite a few,  
7 each of those studies for every and for every  
8 formulation. Each AI could have many formulations.

9           So, last year, our former office director  
10 issued a letter to stakeholders reiterating our  
11 commitment to move to alternative methods and working  
12 with our partners, including other government  
13 agencies, which I'll talk about in a little bit, our  
14 industry partners, as well as the NGOs, particularly the  
15 animal welfare groups, and highlighting the three main  
16 activities.

17           So, critically evaluating, which studies we really  
18 use to make our decisions, expanding acceptance of  
19 alternative methods, and then reducing barriers to  
20 developing alternatives and also accepting them. So,  
21 some of those barriers include challenges of data  
22 sharing between companies, as well as international  
23 harmonization in acceptance of new methods. For  
24 example, if one country still requires the animal  
25 test, then registrants still have to do that test,

1 regardless of whether other countries accept  
2 alternatives.

3 So, internally we have an acute tox 6-pack  
4 workgroup. This has representation across the office.  
5 We meet generally biweekly to talk about recent  
6 progress, new projects coming up. Then, we also have  
7 an external stakeholder group. We meet regularly to  
8 discuss our goals and upcoming projects on how we can  
9 cooperate.

10 Our last meeting was at the Society of  
11 Toxicology meeting that was just in March in  
12 Baltimore. That month we also had two webinars, one  
13 on the eye policy or eye irritation and one on skin  
14 sensitization. We'll be having some follow-up calls  
15 about those. If you're interested in joining the  
16 stakeholder group, contact Shannon Jewell to  
17 get on the list and get the invites.

18 We also have a public docket where we put  
19 our draft guidance for comments. We also put our  
20 final guidance in there. The final guidance also goes  
21 up on the website. The docket also holds our meeting  
22 notes and minutes.

23 So, back to our other federal partners,  
24 ICCVAM, which is one of my favorite acronyms, is the  
25 Interagency Coordinating Committee on the Validation

1 of Alternative Methods. It's comprised of all 17  
2 federal agencies that either require toxicity data or  
3 use it in some way to disseminate information for  
4 safety testing purposes.

5 The scientific support for ICCVAM is  
6 NICEATM, which is another great acronym, the NTP  
7 Interagency Center for Evaluation of Alternative  
8 Toxicological Methods, this is within NIH, and they do  
9 all the analysis or a lot of the analysis in  
10 modeling to support investigating these methods.  
11 They've been invaluable in this process.

12 Going back to the first activity, critically  
13 evaluating, which studies form the basis of our  
14 decision, the acute dermal waiver guidance was issued  
15 in March 2016. This is a collaboration between EPA  
16 and NICEATM to determine the relative contribution of  
17 the oral test and the dermal test to decide what  
18 category goes on the label.

19 After the draft went out in March, we  
20 finalized it in November. And we're already receiving  
21 waiver requests for the dermal study, given an  
22 acceptable oral study. We're even granting those  
23 waivers. So, currently, we receive about 200 to 300  
24 dermal formulation tox tests every year. At about 10  
25 animals per test, that's about 2,500 animals per year

1 saved through this one waiver.

2 So, here are the three other tests listing  
3 the OEC alternatives. They're on the right as  
4 starting points. Then I'm going to talk about the eye  
5 irritation BCOP, which is the Bovine Corneal Opacity  
6 Permeability Test. We have an eye policy in AD to  
7 accept the BCOP as an alternative to eye irritation  
8 for antimicrobial cleaning products.

9 Right now we're trying to expand this to  
10 conventionals. We have an in vitro/in vivo data set  
11 already provided by industry voluntarily that NICEATM  
12 is analyzing. Dave Allen, in particular, at NICEATM  
13 has preliminary results already and has shared those  
14 both through the webinars that we held in March and at  
15 the SOP meetings.

16 There are some gaps in the data, so we'll  
17 probably need to do some perspective testing, which  
18 we'll be discussing in an upcoming call in June to fill  
19 in those gaps so we can finish that analysis.

20 For skin sensitization, ICATM is a group of  
21 international regulatory bodies, so representing the  
22 United States. So (inaudible), part of ICATM, EU,  
23 Japan, CREA, Canada, Brazil, and China, and more than  
24 20 other regulatory authorities met in Italy to  
25 discuss how to come to an agreement on potential IADAS

1 for skin sensitization and identify the obstacles to  
2 doing that.

3 One of the things to come out of that  
4 meeting, the alternatives, including in vitro, in  
5 chemico, in solico, so computer-based models, used in  
6 combination with each other were actually comparable  
7 or better than the animal tests, which is the LLNA,  
8 the Local Lymph Node Assay, in mice.

9 So, the United States, Canada, and EU  
10 drafted an SPSF, which I don't know what that stands  
11 for, it's something in French, to submit to the OECD.  
12 It's basically a project proposal to say, yes, let's  
13 go ahead and develop this performance-based guideline  
14 to accept alternatives. It's performance based to be  
15 more flexible, less prescriptive, and encourage more  
16 innovation. So, that was just accepted I think a week  
17 ago, so there will be a lot of activity on this one in  
18 the coming year.

19 So, the final area of activity is reducing  
20 barriers to adopting alternative methods. In early  
21 2016, EPA released a process for establishing and  
22 implementing alternative approaches. This is meant to  
23 be a transparent way to evaluate approaches and then  
24 implement them in a step-wise process. One of the  
25 things this document addressed was the applicability

1 of 6(a)(2) reporting, which came up as a concern  
2 with alternatives, would it trigger reporting  
3 requirements from new tests that were being developed.

4 It's addressed in this policy in more  
5 detail, but basically, the Agency will only issue a  
6 policy on accepting alternatives if it's clear how we  
7 will use the data and how it fits in with the rest of  
8 what we already know.

9 Right now, we also have a pilot that started  
10 in December to collect both oral and inhalation  
11 formulation LD50s for chemicals, along with a GHS  
12 equation for that formulation. So, the equation is  
13 just adding up the LD50s of the components of the  
14 formulation. Then, the idea is to compare the two so  
15 that potentially that equation can replace both of  
16 those tests.

17 We're still collecting data, so this is a  
18 plug to submit data if you're a registrant. The  
19 equation is shown up there. I don't think it's that  
20 complicated, but it looks complicated. Like I said,  
21 that pilot started in December, and we'll run it until  
22 we get enough data to analyze.

23 Finally, we're also looking at potentially  
24 adopting the GHS categories for the hazard portion of  
25 the label. GHS stands for globally harmonized system.



1     It's what Europe and a lot of the world uses. We have  
2     our own test categories. The challenge here is  
3     adopting OECD guidelines that are in the GHS system  
4     for acute tox hazard categories so then we have to cross  
5     walk between our system and theirs, which is not  
6     straightforward for some tests.

7             One potential thing that could reduce  
8     barriers, but this would require a rulemaking process  
9     and it's pretty complex, the science and policy issues  
10    involved.

11            So, that brings me to our charge question to  
12    you all. In light of the resources required to write  
13    a rule and then move to a different system on the  
14    labels, all labels, what are the science and policy  
15    issues that EPA should consider? I think you were  
16    given a separate update just on this topic.

17            Kaitlin Keller in FEAD, Field and  
18    External Affairs Division, is leading a separate  
19    workgroup internally just to explore the possibility.  
20    I think in the Q&A session, we can talk about it a  
21    little more.

22            Are there any other questions?

23            MR. KEIGWIN: Gabrielle?

24            MS. LUDWIG: This is following up from what  
25    was in the written materials that were handed out

1     beforehand. You've indicated this was a lot of work,  
2     but what I couldn't quite figure out was how much  
3     would it shift current categorizations if you moved to  
4     the existing international one in terms of what you  
5     currently have? Is it just like a few compounds, a  
6     lot of change? I mean, I understand there's the  
7     bigger picture, but in terms of going from a moderate  
8     to a toxic or highly toxic to a moderate or something  
9     like that.

10           MS. LOWIT: I was looking for Kaitlin back  
11     there. The short answer is, at some point as we start  
12     -- I think one of the science steps is actually to do  
13     that analysis, which we haven't done. That said, the  
14     difference between the GHS categories and the EPA/OPP  
15     categories are not huge. There are a couple of  
16     exceptions to that. I think inhalation is just  
17     qualitatively different.

18           They're not hugely different, but that  
19     doesn't mean there aren't any chemicals that wouldn't  
20     change as we moved over. But I think it's also  
21     realistic to think about that there are tens of  
22     thousands of labels. None of that would happen  
23     overnight.

24           MR. KEIGWIN: Pat?

25           MS. BISHOP: Thanks, Garland, for the

1 update. I had a few questions and/or comments. First  
2 of all, on the dermal tox waiver, this, of course with  
3 EPA, is probably just a formulation. As you're  
4 probably aware, Health Canada Pesticide Management  
5 Regulatory Agency did a similar analysis looking at  
6 oral versus dermal. They came to much the same  
7 conclusion as you did, that as long as you had the  
8 oral data, you really didn't need the dermal because  
9 it was very rarely ever more toxic through the dermal  
10 route.

11 They also came to the conclusion that they  
12 could issue waivers for active ingredients as well,  
13 because they did the analysis for AIs and came to the  
14 same conclusion.

15 So, my question is, is EPA considering this  
16 to harmonize with Canada in this respect? If you're  
17 not, why not? That's my first question.

18 Secondly, I was just curious to know how  
19 many of the additivity equation data sets have you  
20 received? If you haven't received any, is there  
21 anything we can do to help push that along? I mean,  
22 we work with Crop Life on trying to send out an e-mail  
23 to registrants to try to participate in this. So, I  
24 was just curious to know if you've gotten any more  
25 since then?

1           Just finally on the GHS issue -- again,  
2   we're speaking more from animal welfare, trying to  
3   reduce animal testing. A lot of the alternatives are  
4   designed to work with the GHS system, as you know,  
5   versus the EPA system in which you have to do some  
6   major -- I don't know if it's major, but they do have  
7   to do some fiddling with the data to try to figure  
8   categories.

9           So, from our point of view, we certainly  
10   would like to see EPA move to GHS. I would think from  
11   industry's standpoint, having one system instead of  
12   two or more would be beneficial to them in the long  
13   run as well. That's just a comment from our  
14   perspective. Let me know the answers to my questions  
15   if you can.

16           MS. LOWIT: That was a lot. I'll take the  
17   second one first because that's the easier one.

18           So, your second question was about the GHS  
19   pilot. We've been running the GHS pilot since  
20   December. We're now into May. We have a whole number  
21   one submission. Dow AgroScience, a number of months  
22   ago, kindly provided the analysis of over 200 of their  
23   own products, so we have something, the Dow analysis,  
24   which has actually been recently published in the open  
25   literature, but only one submission under the pilot.

1           A number of companies keep reassuring us  
2   that we're getting some more big data dumps, but we  
3   haven't seen those yet. We're hoping that they do  
4   arrive pretty soon. We're open to anyone who has  
5   questions about how to do that, because we've had a  
6   few questions on that. We're happy to talk offline or  
7   via e-mail on how to make that happen.

8           The first one is the harder question. So,  
9   your first question was about expanding the dermal  
10  formulation waiver to the dermal active ingredient  
11  assays. You're not the first person to ask us that.  
12  In fact, Kate Willett from the Humane Society has been  
13  asking the same question. We've had some e-mail  
14  dialogue with her, too.

15          In the immediate term, we're not going to  
16  make that move. That doesn't mean eventually that we  
17  won't make that move, but right this moment we're not.  
18  That's almost entirely driven by our needs for our  
19  ecological risk assessors. As we continue to develop  
20  and evolve, particularly in the endangered species  
21  space, we need to ensure that the data are available  
22  that they may need. I think the ESA issues are  
23  continuing to evolve.

24          We're not going to move to eliminate that  
25  dermal tox study right now. That doesn't mean a year

1 or two years from now we won't be in a position to  
2 think about doing that, but right now is not the right  
3 time.

4 MS. BISHOP: Just curious, how is Canada  
5 getting past that? I mean, I don't know if you know,  
6 but how come they don't need the data but we do?

7 MS. LOWIT: I think you would need to ask  
8 them that question.

9 MR. KEIGWIN: Ray.

10 MR. MCALLISTER: I'm going to ask some basic  
11 questions just to make sure I understand things. The  
12 6-pack is required on a formulation basis, is it not?  
13 Each formulation or different formulations generally  
14 require a new 6-pack?

15 MS. LOWIT: That's right. So, they come  
16 for the individual active ingredient but also for the  
17 formulation.

18 MR. MCALLISTER: And you have a separate  
19 similarity clinic to compare formulations and decide  
20 when it's different enough to require a new 6-pack?

21 MS. LOWIT: That's right. So, outside of  
22 this effort to modernize the 6-pack bringing in the in  
23 vitro studies but also some of the computational  
24 approaches. We have also recently improved our SIM  
25 Clinic approach. What's the SIM Clinic? The SIM

1 Clinic actually has a new name. It's a group of  
2 scientists who look at the acute tox studies and they  
3 look for opportunities for waivers.

4 So, the real point of that group is to  
5 compare formulation A, which exists, to formulation B  
6 which is new and see if they're similar enough that  
7 you can waive the study for formulation B, which is  
8 also one of the best ways to eliminate animal testing,  
9 is just simply to waive the study based on existing  
10 information. That's the function of that, and it's  
11 been working for a long time.

12 MR. MCALLISTER: So, I think you've answered  
13 my ultimate question, which is how do those two groups  
14 work together.

15 MS. LOWIT: They're actually working in  
16 concert together. There's actually a lot of overlap  
17 between the acute tox workgroup and what used to be  
18 called the SIM Clinic.

19 MR. MCALLISTER: Okay.

20 MR. KEIGWIN: Any PPDC members on the phone  
21 that want to speak to this?

22 (No verbal response.)

23 MR. KEIGWIN: Gabrielle.

24 MS. LUDWIG: So, I think two things. One is  
25 I appreciate that you point out that you're working on

1     this on a national level because if you don't have --  
2     make life easier for the registrants or change the  
3     number of animals used in the testing. So, I think  
4     this is another case where working with OECD or  
5     whatever the processes are of the government is  
6     critical.

7             Then, I'm not a risk assessor so I don't get  
8     all of this. But I do work on international trade  
9     issues. So, from my perspective, anything that is  
10    harmonized internationally is better than each of us  
11    doing our own thing from an efficiency perspective.  
12    So, even though it may be hard to go through the  
13    transition, my gut reaction is to say go ahead and  
14    make the transition.

15            MR. KEIGWIN: I'm seeing lots of nods in the  
16    affirmative. Thank you both.

17            We're going to transition into our kind of  
18    what we've called in past years as updates in a minute  
19    type of thing. Kaitlin, why don't you come up to do  
20    the GHS one, since it's kind of topical given what we  
21    just discussed.

22            One point that I'll make, there are some  
23    updates in your packets which we're not going to take  
24    comments on. One of those I just wanted to provide an  
25    update to the update. That's the one regarding



1     glyphosate. Subsequent to us preparing materials for  
2     this meeting, Canada's pest management regulatory  
3     agency issued an update to their regulatory position  
4     on glyphosate.

5             I think the fact sheet mentions a June 2015  
6     determination. They did reaffirm their determination  
7     regarding the lack of a carcinogenic potential for a  
8     glyphosate last week. So, the most recent date would  
9     be April 2017 for Canada's assessment.

10            With that, Kaitlin, do you want to just give  
11     us a very brief overview of where we're at with GHS?  
12     Then we'll see what questions we have.

13            MS. KELLER: Hello, my name is Kaitlin  
14     Keller. I'm in the Field and External  
15     Affairs Division here at OPP. As was already kind of  
16     discussed as part of the acute tox modernization, we  
17     have an internal workgroup that was established last  
18     year, specifically looking at the globally harmonized  
19     system of classification and labeling of chemicals. A  
20     lot of this stems out of the work that was being done  
21     and moved forward on the acute tox 6-pack, and  
22     additionally, just because of the harmonization that  
23     would result of it.

24            So, the workgroup has been looking at  
25     different options for GHS, implementation for

1 pesticide labels. At this point we've been looking  
2 just for adopting the GHS category use for the acute  
3 tox, the human health portion, and the physical  
4 hazards on the label.

5 As a little bit of background, GHS is a  
6 global initiative that stems out of the UN. It was  
7 adopted in 2003. It's for classifying and  
8 communicating chemical hazards on chemical labels and  
9 safety data sheets, including product identifiers,  
10 cautionary statements, pictograms, and signal alerts.  
11 It encompasses physical health and environmental  
12 hazards. Again, we're just looking at some of those  
13 categories that relate to pesticides now, so no new  
14 label elements, just converting those that are already  
15 on the label to be GHS compliant.

16 And so, at this point, you can kind of walk  
17 through the fact sheet. I think that was provided  
18 already. But one thing to note is that OSHA of course  
19 has already implemented GHS, so the SDS are compliant  
20 with GHS. The pesticide labels can often be  
21 inconsistent with that. So, that's one of the main  
22 reasons across federal government I think that there's  
23 an interest in harmonization there as well.

24 So, if there are any questions -- I'll just  
25 kind of leave it at that, but I can take questions.

1 MR. KEIGWIN: Ray.

2 MR. MCALLISTER: Crop Life has long opposed  
3 GHS implementation on pesticide labels. We haven't  
4 yet found a reason to change that position. I won't  
5 take the time to go into the reasons for that, but in  
6 light of the work you're doing now, we will look once  
7 more. But don't anticipate changing our position.

8 MS. PALMER: I just had a clarifying  
9 question. It says that OPP is not considering chronic  
10 health hazards that would add additional label  
11 requirements. So, is that just because it's too much  
12 work and too much trouble or what's up with the  
13 chronic?

14 MS. KELLER: I think that we were mostly  
15 just looking at converting what's currently on the  
16 label to GHS and not considering additional label  
17 elements. Again, the acute tox, a lot of that stems  
18 from the use of that from the science perspective as  
19 well and kind of moving towards OECD being able to  
20 accept OECD assays for those. So not requiring  
21 additional data and not requiring additional label  
22 elements behind it.

23 MR. KEIGWIN: Komal.

24 MS. JAIN: Thanks. Komal Jain from the  
25 Biocides Panel. I just want to echo the same concerns

1       raised by Ray. The Biocides Panel has been  
2       communicating on this issue with EPA for a number of  
3       years. We look forward to having some more detailed  
4       conversations about our concerns.

5               MR. KEIGWIN: Nina.

6               MS. WILSON: So, just to follow on, the  
7       biopesticide industry would have some concern moving  
8       to GHS because I think with signal word changes on  
9       some of our types of pesticides might lose some of  
10      that advantage that we currently have on signal words.

11              MR. KEIGWIN: Dawn.

12              MS. GOUGE: I just feel that a move towards  
13      GHS is the right move. It's the right direction to  
14      move. I understand that it may place burdens and  
15      additional work on both the Agency and industry, but I  
16      can't believe that it wouldn't be advantageous  
17      ultimately in the long run.

18              MR. KEIGWIN: I don't know if Steve Bennett  
19      is on the line, if the CSPA wanted to weigh in on this  
20      one or not.

21              MR. BENNETT: Steve Bennett. I don't think  
22      we have any specific comments that I'm aware of. I  
23      know this is something our members have paid  
24      particular interest in, but I don't have any specific  
25      comments.

1           MR. KEIGWIN: Cynthia, did you have another  
2 comment? All right, thank you -- certification and  
3 training. So, Jackie and Kevin are doing this update.

4           MR. KEANEY: You have in your package the fact  
5 sheet for both regulations. The existing regulation  
6 for worker protection has two implementation dates.  
7 Many of the provisions are in place, but there's a  
8 delay until January of '18 to make the full regulation  
9 implemented so certain training materials and  
10 compliance materials can be out and circulated.

11           We've gotten response from the states that  
12 they feel there's not enough time to adequately engage  
13 with stakeholders and prepare the folks that need to  
14 be prepared through compliance materials and training  
15 materials to be able to work within that time frame.

16           So, we've had a few petitions, requests, a  
17 number of states made requests, NASDA has made  
18 requests to essentially change the second date, push  
19 the date out. We acknowledged the receipt of the  
20 letters and receipt of the requests from NASDA and as  
21 yet have not reached a point where we are at a  
22 decision point for that.

23           The certification regulation is on hold as  
24 far its implementation date is subject to review.  
25 It's on hold until May 22nd. We've also gotten a

1 number of responses from major stakeholder groups  
2 essentially supporting what we did between proposal  
3 and final. In the proposal, we focused on 21 areas of  
4 change. In the final, as a result of the comments,  
5 very insightful comments from state groups, we moved  
6 away from the proposal position in 15 of those 21  
7 issues.

8           The Association of Pesticide Control  
9 Officials have sent letters complimenting us on that  
10 essentially cooperative or collaborative federalism in  
11 making those changes and making it much more flexible  
12 and essentially doable in their assessment.

13           We've gotten that type of public support  
14 from the National Pest Management Association, and in  
15 a certain way from NASDA, and from the National Aerial  
16 Applicator Association. So, I think we've adequately  
17 responded to comments to create a much more flexible  
18 and appropriate time frame for implementation of that  
19 regulation.

20           The Pesticide Policy Coalition essentially  
21 supports the position we arrived at but had some  
22 concerns about the minimum age requirements. So, they  
23 were requesting an extension of the implementation  
24 date until we could address -- they were asking us to  
25 address the minimum age requirement.

1           So, there's a lot of things on the table for  
2   us with both of those regulations. Obviously, they'll  
3   be part of the response, I suspect, tomorrow as far as  
4   regulatory review. We're obviously open to the  
5   suggestions that have been sent.

6           MR. KEIGWIN: Thanks, Kevin. Question or  
7   comments on either of these? We'll start with Wayne,  
8   then Jim, then Virginia.

9           MR. BUHLER: Thank you, Kevin. I appreciate  
10   the updates. Comment on one and a question on the  
11   other. First the comment on WPS from a trainer  
12   perspective. It seems very difficult, challenging at  
13   the very least, to train on the implementation of the  
14   applicator exclusion zone.

15           I know that isn't an item until 2018 for  
16   full implementation, but I just want to go on record  
17   as perhaps an organization, and personally as a  
18   trainer, that it would be very difficult for us to be  
19   able to reach a point in which that could be  
20   communicated clearly. I think it would be rather  
21   onerous even from the enforcement standpoint. So,  
22   it's my hope that EPA would reconsider either removing  
23   or adjusting that.

24           MR. KEANEY: That has been raised by a number of  
25   commenters, and obviously we'll be considering that.

1 We do sympathize with the complexity of the enforcing  
2 or training on that.

3 MR. BUHLER: Thanks. The question for the  
4 certification rule is in the middle of the page you  
5 have a bullet item under final changes that non-  
6 certified applicators under supervision would go  
7 through an enhanced pesticide safety training or other  
8 qualification. What is meant by that? Is it a  
9 separate program? Is it something that's considered  
10 being developed by states?

11 MR. KEANEY: It's training that's quite similar  
12 to the handler training under the worker regulation.

13 MR. BUHLER: But it is separate and  
14 distinct?

15 MR. KEANEY: It's under the certification so it's  
16 separate and distinct, but it's essentially the type  
17 of training you get as a handler under worker  
18 protection.

19 MR. BUHLER: Okay, thanks.

20 MR. KEIGWIN: Jim, then Virginia, then Dawn.

21 MR. FREDERICKS: Thanks, and thanks, Kevin,  
22 for the report. On behalf of the National Pest  
23 Management Association, you mentioned our support of  
24 the final rule. I think that I just want to publicly  
25 commend the Agency for the process. I think in this



1 case the process worked. We saw a robust comment  
2 period and recommendations from various stakeholders.  
3 Many of those were incorporated in the final rule  
4 which allowed for more flexibility and a more workable  
5 rule. So, thanks for that.

6 MR. KEIGWIN: Thanks, Jim. Virginia, then  
7 Dawn, then Valentin.

8 MS. RUIZ: As a stakeholder who has been  
9 engaged in the rulemaking process for the WPS and also  
10 the Certified Pesticide Applicator Regulation, it  
11 certainly has not been a quick process. Personally, I  
12 have been engaged for 16 years in this rulemaking.  
13 Through that time, I've seen extensive engagement of  
14 very diverse stakeholders.

15 I would disagree that anything in these  
16 regulations are new or surprising or onerous. I  
17 strongly oppose any delay in implementation in worker  
18 protection. EPA is the only agency that has  
19 jurisdiction over worker protection for a work force  
20 that is very vulnerable, very much in need of enhanced  
21 information and training.

22 So, I would strongly urge the Agency not to  
23 delay implementation. I think 20 years is already  
24 long enough for this community to have waited for  
25 these improved safety provisions. I also think that

1 further delay in implementation would put the Agency  
2 at risk for violation of the Administrative Procedure  
3 Act and FIFRA. Thank you.

4 MR. KEIGWIN: Dawn, then Valentin, then Amy.

5 MS. GOUGE: Thank you. Kevin, I'm a bit  
6 worried at the prospect of a delay with regard to the  
7 minimum age. I just wondered if you wouldn't mind  
8 expanding just a little bit on the practical options  
9 for establishing certification programs in Indian  
10 land.

11 MR. KEANEY: Well, prior to this, there were some  
12 forced choices to be made for establishing programs in  
13 Indian country. They could work with existing state  
14 programs, and they felt that compromised their  
15 sovereignty. They could establish their own or they  
16 could work with EPA.

17 We made it more clear how we can work with  
18 the tribal programs, federal to sovereignty to  
19 sovereignty as it were. So, it's in the clarifying,  
20 clarifying what practice was a number of choices, some  
21 of them unfavorable to the tribal rulers.

22 MR. KEIGWIN: Valentin, then Amy, then Liza.

23 MR. SANCHEZ: Hello. As a former farmworker  
24 and as the son of farmworkers, I'm truly happy to see  
25 that we're continuing to look for ways to protect

1 farmworkers. I know that for 20 plus years there were  
2 no actions to protect farmworkers, including their  
3 family members. So, we have 2.5 million farmworkers.  
4 If you have family members, that's a pretty big  
5 number. Some of them are migrants; others are  
6 seasonals.

7           Also, a significant percent of them speak  
8 indigenous languages from Mexico and Guatemala. So, I  
9 think it is very crucial that we continue to look for  
10 ways in which we can protect them, because for many,  
11 many years they have been forgotten.

12           So, I just want to say thank you, and I hope  
13 that we continue down this road so we have some  
14 protections for farmworkers and their family members.  
15 Thank you.

16           MR. KEANEY: Thank you. I would point out that  
17 the revised regulations try to add more training  
18 elements that would be addressing take-home exposures  
19 and protecting families from take-home exposure.  
20 Also, we are committed to providing training in a  
21 manner that's understood, which means the language is  
22 understood. So, in the development of materials, it  
23 will obviously be in English and Spanish, but  
24 obviously as well in other languages that we know  
25 exist as labor segments that need to be reached.

1           So, we did have in the older regulation a  
2   couple of training packages for indigenous language  
3   speakers that were working on orchards. So, we'll  
4   continue that, obviously. We do have a long-term  
5   cooperative agreement with University of California-Davis  
6   combined with Oregon State to develop materials.

7           It's called the Pesticide Educational  
8   Resources Collaborative. If you go on their web site,  
9   you can see the pretty extensive array of training  
10  materials that have been developed and will continue  
11  to be developed. It's capable of being downloaded and  
12  used for anyone who needs them. That will go on and  
13  will expand into training materials for the  
14  certification regulation as well.

15           MR. KEIGWIN: Amy, then Liza, then Richard.

16           MS. LIEBMAN: Thanks, Kevin, for giving us  
17  the update. I just want to also echo a little bit of  
18  what Virginia is saying. I've been involved with a  
19  diverse group of stakeholders in a really important  
20  process that the Agency undertook.

21           So, starting in 2001, I was at a stakeholder  
22  meeting where there was industry, farmworkers,  
23  different groups all impacted by how pesticides impact  
24  workers. I continued as a stakeholder throughout the  
25  process.

1           In 2006, there was a subcommittee of the  
2   PPDC that was beginning to address worker protection  
3   safety. I participated in that, again along with a  
4   diverse group of stakeholders from many different  
5   perspectives.

6           So, while frustrated at times with the speed  
7   of the revision of the WPS, that process is incredibly  
8   important as we look at what we have today because we  
9   got so much input. The Agency got so much input along  
10  the way. It got input when you release the comments  
11  for public comments.

12          What you have come out with, really, is an  
13  important step forward for the workers who put food on  
14  our table. Quite frankly, it's a moderate step  
15  forward. It's not a radical new rule. It's not a  
16  radical revision. There are some really, really  
17  critical pieces, such as a minimum age, training,  
18  notification, all very, very important improvements  
19  that we can stand behind.

20          I would hope that every single stakeholder  
21  in this room would rally behind this rule that has  
22  come out and is designed and is the only one, as  
23  Virginia pointed out, that is protecting farmworkers.  
24  So, I'm a little bit baffled at the calls for some  
25  delays when we look at the painstaking process that

1 both stakeholders and the Agency went through to get a  
2 rule out. So, I really advise the Agency to move  
3 forward with the time table that you put forth. I  
4 think there's a number of stakeholders out there that  
5 are here to help you as you implement it.

6 There will be bumps. There will be some  
7 questions. There will be challenges. No one says  
8 it's easy. But if we're about protecting workers,  
9 which is what is required under the law, then we need  
10 to move forward on this. There should be actually no  
11 delay. I would hope that everyone in this room would  
12 rally behind this.

13 I mean, I'm dumbfounded that anyone is  
14 calling for a delay. It's really upsetting. I really  
15 want us to remember this process that you went  
16 through. Remember the science that's behind this and  
17 the data that's behind all this. Know that we have a  
18 rule that involves input from everybody, and we need  
19 to get it out there.

20 MR. KEIGWIN: Liza, then Richard.

21 MS. FLEESON TROSSBACH: Thank you. I have  
22 comments on both WPS and C&T. First of all with the  
23 Worker Protection Standard, I would agree. I don't  
24 think any stakeholder, and I know I can speak for  
25 state lead agencies, we absolutely support enhanced

1 worker protection, worker safety issues for  
2 farmworkers, for all occupational users and users of  
3 pesticides.

4 I think one of the issues for state-lead  
5 agencies and the idea of the implementation date is  
6 our ability to have access to the individuals who need  
7 to be in compliance. When the rule went into effect  
8 or was going through this process, we were told we  
9 were going to have the resource materials that we need  
10 in a timely manner.

11 Unfortunately, that process took a little  
12 bit longer. So, because of that, our ability to have  
13 access to your agricultural producers and farmworkers  
14 and those folks were delayed, and we did not have as  
15 much access. It's just not as easy as here's the  
16 information, go forth and start to implement this.  
17 There's a compliance assistance process that's needed.

18 We firmly believe in educated communities, a  
19 compliant community. State lead agencies are out  
20 doing inspections and doing those investigations,  
21 doing the work we need to, but it takes time to come  
22 into compliance and to bring people into compliance.  
23 While some of the issues or the changes may seem  
24 logical to us, there are concepts that are difficult  
25 for people to understand.

1           The AEZ is a perfect example. That  
2       was not included in the original proposal. When the  
3       final rule came out, that was a complete change, and  
4       it took us time to figure that out. So, now we're  
5       trying to make people understand how to do what they need  
6       to do and come into compliance.

7           So, it's not a matter that it's not out  
8       there and we're not working towards it, but it takes  
9       time. It took time to get the rule in place, and it's  
10      going to take time to get it fully implemented to get  
11      people into compliance. I think that's the  
12      perspective from the state lead agencies.

13          We're not saying don't implement the rule,  
14      don't put it into effect, don't make people start to  
15      work towards that. But be realistic in that it's  
16      going to take some time to reach those growers of  
17      agriculture producers out in the field.

18          So, states are out there doing it now.  
19      States have the ability to exercise prosecutorial  
20      discretion. I mean, we're doing inspections and  
21      investigations. But depending on the situation, there  
22      may or may not be action, because we understand -- we  
23      believe that you need to educate people first and go  
24      from there. So, that's for the Worker Protection  
25      Standard.



1           For the C&T update, I want to echo what many  
2       folks have said. We appreciate the Agency's  
3       willingness to work with stakeholders. The initial  
4       proposal to the final had dramatic changes. Much more  
5       flexible. Addressed many of the issues that state-  
6       lead agencies brought up.

7           As far as the delayed implementation, once  
8       again I think state lead agencies support enhanced  
9       competencies for applicators. Want to ensure that  
10      people are applying pesticides properly and providing  
11      for human health in the environment.

12          But there's a lot of uncertainty right now  
13      with state lead agencies. One, even though the  
14      certification training rule has been out since early  
15      December, it's quite complex. States are still going  
16      through the process of trying to determine what they  
17      will need to do in their own states to make changes to  
18      come up to that minimum baseline.

19          There are resources issues. Funding is  
20      uncertain for the state tribal assistance grants,  
21      which many states rely on to be able to have resources  
22      towards putting that into place. I think that comes  
23      into play.

24          I don't think that delaying the  
25      implementation is going to impact the ultimate result.

1 I believe that state lead agencies have had  
2 certification programs for many, many years, very  
3 robust programs that have evolved substantially, many  
4 of which are well beyond the current requirements or  
5 the requirements in the new C&T.

6 So, I don't feel like the program is going  
7 backwards in any way if there is a delayed  
8 implementation. The reality is that many states will  
9 have to go through the regulatory process, which,  
10 depending on the state, can take a very long period of  
11 time.

12 So, the current time frame, while it may  
13 seem like a long time to be able to come into  
14 compliance in government time, it may not necessarily  
15 be adequate. I think there are a couple issues that  
16 probably need some more discussion, like the minimum  
17 age requirement. I think probably in some  
18 circumstances you will have full support; in others,  
19 it may not be right for that particular state. I  
20 think some of those issues probably need to continue  
21 to be discussed.

22 So, in that particular case, I just don't  
23 think delaying is going to negatively impact the  
24 certification program on a national level, because I  
25 believe the certification program is quite evolved and

1 is doing a good job now. As we move forward, we'll  
2 even do a better job in the future. Thank you.

3 MR. KEIGWIN: Richard.

4 MR. GRAGG: I can appreciate all of the  
5 conflicts and different things that go into making all  
6 of this work. But I just wanted to say two things. I  
7 think the EPA is about protecting the environment and  
8 human health, then I would expect that the most urgent  
9 about protecting the people who are ground zero from  
10 these pesticides versus people who are on the consumer  
11 end that may only be getting a little bit.

12 Then, secondly, I think worker protection  
13 standards and certifications is even more important  
14 and urgent based on our previous discussion when we  
15 want to talk about pollinator protection. These are  
16 the people that are going to be spraying and  
17 manipulating and using the stuff out in the field.  
18 We're going to rely on them for the pollinator  
19 protection issue, ultimately.

20 MR. KEIGWIN: Okay, thanks, Kevin. So, the  
21 next update is on resistance management. Wynne and  
22 some others from BEAD will come on up.

23 MR. JONES: Hi, I'm Arnett Jones from BEAD,  
24 Biological and Economics Analysis Division. We have  
25 some background materials and would make ourselves

1 available for some questions. I'll give you an update  
2 on some of the work we're doing in resistance  
3 management.

4 As you know, resistance has become a very  
5 important economic and biological issue in terms of  
6 effectiveness of some of these compounds that we  
7 license for pest control. As a result of that, we  
8 undertook two initiatives. One was a general labeling  
9 initiative, which is an update of a 2001 pesticide  
10 registration notice, a PR notice. Nikhil  
11 can perhaps go into some detail on it if you want a  
12 little more detail.

13 But basically, it's a very strong  
14 encouragement for companies to put the mechanism of  
15 action on their labels in a very distinct and clear  
16 way so that growers would have access to that. That  
17 information would be very useful to them in terms of  
18 understanding the mode of action of their particular  
19 compound and how they may consider to choose to rotate  
20 their chemistries to practice some pest resistance.

21 Do you have anything to add, Nikhil?

22 MR. MALLAMPALLI: Hi, everyone. My name is  
23 Nikhil Mallampalli, entomologist with BEAD. This PR  
24 notice pretty much mirrors the 2001 PR notice. It gets  
25 into more detail with the guidance that registrants can  
26 put on their labels. It's limited to agricultural

1 pesticides. We've taken comments on this and the other  
2 PR notice that Skee will mention in a minute. We've got  
3 about 19 comments on this PR notice, very good comments  
4 that we think enhance the guidance. We're hoping to  
5 finalize the guidance sometime this summer.

6 MR. JONES: Thanks, Nikhil. The public  
7 comment was very important for that one, as well as  
8 for the second PR notice that deals with herbicides.  
9 That's guidance on pesticide registrants on herbicide  
10 resistance, management, labeling, education, training,  
11 and stewardship. Like the more general labeling  
12 notice, this notice went out for public comment. I  
13 don't remember how many comments we got.

14 UNIDENTIFIED FEMALE: Twenty-seven.

15 MR. JONES: Twenty-seven, thank you.  
16 Anyway, as with the labeling, the suggestions were  
17 very useful, and we actually changed some of the ways  
18 we were thinking about this in terms of how to more  
19 proactively manage resistance for herbicides.

20 If you think about where we are at EPA in  
21 terms of having basically a label as our instrument,  
22 we have made an effort to reach out to a lot of  
23 stakeholders and grower groups, Wheat Science Society

1 and others, USDA, trying to get sort of collective  
2 wisdom and to get the right people behind the  
3 initiative to get growers to be more active in  
4 practicing herbicide resistance.

5 Again, with herbicides, there basically  
6 hasn't been any new real mechanisms of action in  
7 something like 30 years or something like that.  
8 There's a lot of emphasis on the genetically-modified  
9 crops in terms of their importance in managing  
10 resistance.

11 There have been some unfortunate outcomes as  
12 a result of that. So, we're just trying to be more  
13 proactive and are trying to do it in a way that we  
14 think is responsible and will be effective in terms of  
15 getting the result that we want at the grower level.

16 Anything to add, Wynne?

17 MS. MILLER: No. I think the goal for that  
18 PRN, like Nikhil mentioned, is to try to release it  
19 sometime this summer.

20 Folks may recall for that herbicide  
21 resistance management PRN, we had suggested three  
22 categories that center around these elements of  
23 education, stewardship, training, and the labeling.  
24 Depending on which category you fell into, 4 elements  
25 would apply, or 8 elements, or all 11 elements.

1 Surprisingly, we got a lot of people coming back and  
2 saying hey, forget having three different categories.  
3 Let's just focus on one, focus on the high, and make  
4 it apply to all those modes of actions.

5 So, that's kind of what we're looking at  
6 internally, how to craft that. Again, we hope to  
7 release sometime in mid-summer.

8 MR. JONES: Are there any questions on that?

9 MR. KEIGWIN: Richard, I'm not sure if your  
10 card is up from before? All right, Robyn and then  
11 Steven.

12 MS. GILDEN: Thank you for the update. Just  
13 to clarify, this is all just for what the registrants  
14 are going to be putting on the label? Is there any  
15 other kind of techniques that are going to be  
16 associated with best management practices like trap  
17 rotation?

18 MR. JONES: There are two notices. One is a  
19 general labeling, and that is limited to labeling.  
20 But it also has some best practices as well.

21 Nikhil, you want to elaborate on that?

22 MR. MALLAMPALLI: We focus on the pesticide  
23 rotation, rotating modes of action. That's repeated  
24 for all pesticides. But we do mention suggestions to  
25 registrants. Registrants can choose to put whatever

1 other best practices they want to on their label. We  
2 make some suggestions, such as using crop rotation  
3 where relevant. Scouting is suggested throughout,  
4 things like that. I don't know if that is what you  
5 were getting at, but there is some of that in the PR  
6 notice.

7 MS. MILLER: Actually, for the herbicide  
8 resistance management PRN, it went beyond labeling.  
9 It also talked about things like resistance management  
10 plans as well. So, that's where we got into the  
11 stewardship, the training, and again beyond the  
12 labeling.

13 MR. JONES: There's also, if you look at  
14 some of our recent decisions, there are terms of  
15 registration related to reporting resistance, early  
16 identification, remediation, and things like that.  
17 So, again, we are limited to labeling in some specific  
18 ways, but we've really tried to leverage some other  
19 tools that we have, including the other organizations  
20 that put out the best practices, as well as when we  
21 think it's appropriate, the terms of registration on  
22 the stewardship end.

23 MR. KEIGWIN: Steven, then Marc, then Dawn.

24 MR. COY: So, I think that addressed some of  
25 my concerns. I was thinking, what did you do to



1 address the prophylactic use of insecticides?

2 Herbicides are not so much used, but I know

3 insecticides are frequently put on as a just-in-case

4 type scenario.

5 MR. MALLAMPALLI: So, I think back to what's

6 in our insecticide section. The general labeling PRN,

7 of course, covers insecticides. We say that

8 registrants should put on their labels that growers

9 should scout before and after an application. So, as

10 a suggested bit of guidance that registrants can put

11 on their labels, we have put that out there in the

12 PRN.

13 As biologists, we know that sometimes within

14 the pest, they're going to need to apply on a

15 calendar basis. So, that's something that extension

16 would have to play a role in in advising growers. But

17 to the extent that the label can have that, we would

18 like the label to make sure to say to growers scout

19 before and after. Don't just apply prophylactically.

20 MR. JONES: And these are pesticide

21 registration notices. They're advisory in nature.

22 One thing I will tell you, it's a timely question.

23 Yesterday we met with the Insecticide Resistance

24 Action Committee. We've taken on herbicides first

25 because we had some painful examples of the

1 marketplace frankly not doing a great job in terms of  
2 managing resistance there.

3 But in terms of prescriptive stuff on the  
4 label related to prophylactic use, there's nothing  
5 like that. But we are trying to -- these are advisory  
6 documents. We're trying to raise a level of  
7 awareness. We took on herbicides first because that  
8 was the case that was calling out for it. We have  
9 thought about insecticides, but we haven't gone down  
10 the road with them the way we have with herbicides.

11 MR. KEIGWIN: Marc.

12 MR. LAME: So, I think you've answered a  
13 number of things that I'm concerned about, again which  
14 is we look at the registration, which, for all intents  
15 and purposes, is permitting and then monitoring for  
16 compliance, enforcement, and technical assistance.  
17 Because this is advisory, you're covering most of  
18 those things except for enforcement.

19 I guess at some point if I was remaining on  
20 the committee, I would like to hear more about, since  
21 this is advisory, what the different user groups or  
22 industries are doing with regard to some type of  
23 enforcement, market-based enforcement or something.  
24 Obviously not Agency-based because you guys aren't  
25 going there with resistance.

1           My expertise is in diffusion of innovation,  
2   how to get communities to adopt new things. I guess I  
3   don't see that diffusion process playing out here.  
4   I've seen some of the same old stuff that sounds nice  
5   but it's probably going to have to wait until things  
6   go away and maybe come back some day or never come  
7   back before something is done.

8           I think both for the growers and for  
9   industry itself, it would probably be best to have a  
10  more organized and well-managed effort to diffuse the  
11  innovation of prevention in resistance management.  
12  I'm not seeing it.

13          So, I would recommend that in the future as  
14  far as diffusion of innovation, particular to public  
15  health. I know that these are not public health  
16  insecticides. I mean, my colleague will mention this  
17  no doubt, but we're reaching a crisis stage. At what  
18  point does society say that we're going to get tougher  
19  on these things for human health.

20          My good friend Ray over here might be  
21  surprised to know that I do consider some of these  
22  pesticides as valuable tools. I would like to see  
23  them preserved. But it's going to take more than a  
24  tacit response. So, just my comments.

25          MR. JONES: I mean, we struggled with this,

1     okay. We've done the best we can in terms of trying  
2     to get the right people educated. We've seen some  
3     movement out there in terms of grower behavior.  
4     Somewhat related to what you're talking about, some of  
5     the registrations now are time limited. Part of the  
6     reason for that is because of the resistance potential  
7     for repeating the glyphosate experience, for example.

8             So, we're looking for creative ways to use  
9     the little bit of power that we have. I think we've  
10    been pretty successful in getting the USDA and  
11    resistance action committees and the Wheat Science  
12    Society and the Entomology Society involved in this.

13            But we hear you, and we'll take that into  
14    consideration. If you take a look at the terms of  
15    registration, there's a little bit in there. There's  
16    some books in there that are a little more solid.  
17    They have some teeth in them in terms of concern for  
18    the problem.

19            MS. KUNICKIS: I just want to  
20    respond. In case you weren't aware, there's a huge  
21    effort by some of the professional societies to do  
22    outreach on resistance management. For example, the  
23    Wheat Science Society, over the last year, have been  
24    holding listening sessions with growers and other  
25    stakeholders on how to implement and get information

1 out about the issue of resistance management.

2 Next week or the week after in Colorado is  
3 the Global Resistance Challenge. It's an  
4 international meeting where the whole week will be  
5 focused on resistance management. Lots of folks will  
6 be there. Lots of conversation.

7 USDA and EPA will be participating with the  
8 Wheat Science Society to do all kinds of outreach. A  
9 lot of documents have been prepared. Informational  
10 pamphlets, et cetera, have been put out and also by  
11 some of the grower groups. So, there is a lot of  
12 effort. We'd be glad to work with you or engage you  
13 if you want information about that.

14 MR. LAME: Well, I would be happy to help.  
15 I don't think I need much more information on it. As  
16 much as I hate to say it, this is less of an educator  
17 thing, as a former extension person and current  
18 entomologist, enthusiastic.

19 Peer development is the most important  
20 thing. So, the grower group thing is good. I'd just  
21 like to see a tougher response. Last time you  
22 mentioned the limits on registration. I think that's  
23 the best thing the Agency can do, or probably the only  
24 thing the Agency can do at this point.

25 MR. JONES: Thank you Sheryl for adding on

1 to that. The societies, you talk about behavior and  
2 economics being a big factor. You go to these  
3 meetings now and there's social scientists that are  
4 giving presentations (inaudible) sociology is back to  
5 sophomore college. But they turn out to be these  
6 extremely interesting talks about how to motivate  
7 behavior. I think the societies have done a great job  
8 in terms of getting the word out and spreading the  
9 word. We're starting to see it in the behavior now of  
10 the growers.

11 MR. KEIGWIN: So, I'm just going to go with  
12 the rest of the cards that are out. We've got two  
13 other topics to cover before the break. So, Dawn,  
14 then Donnie, then Gabrielle.

15 MS. GOUGE: Thank you. I just wanted to  
16 raise an issue. Marc alluded to the public health  
17 crisis not being resistant to mosquito adulticides.  
18 So, I wanted to put that on your radar if it's not  
19 already on your radar.

20 We have a small army of people around the  
21 country right now ramping up to do bottle bioassays to  
22 see if they can kill, having had at least a two or  
23 three years recently when it's been a very serious  
24 struggle to kill mosquitoes on the wing with, let's  
25 face it, two modes of actions that we have available.

1           I have an office next to Peter Allsworth  
2     (phonetic), who is a cotton entomologist, and he brags  
3     openly about the rules and regs that you have to stick  
4     to with regards to how many times you can use  
5     pyriproxyfen twice in a season. And he rotates it out  
6     with this, that, and the other. Meanwhile, the  
7     mosquitoes are being nuked. We try not to use the same  
8     thing for more than two years. Those applications can  
9     happen maybe 15 or 16 times in one season.

10           So, it's not that we're looking for  
11     resistance to be a crisis. It's already a crisis.  
12     We're trying to find pockets of areas. We just know  
13     that basically the choice that we have right now, we  
14     need to be relying on other things. No need to carry  
15     on doing what we've been doing. It's not working.  
16     Thank you.

17           MR. KEIGWIN: Donnie, then Gabrielle, then  
18     Ray.

19           MR. TAYLOR: This is more information than  
20     anything else. One of the soybean groups and the  
21     leading wheat scientists from across the United States  
22     has created a program called Take Action. Actually,  
23     the website is take action on weeds dot com. I highly  
24     recommend it. It's a great program. Talks about  
25     different groups and categories of chemistries that

1       are available out there.

2               MR. KEIGWIN:  Gabrielle, then Ray, then  
3       Cynthia will be the last one for this session.

4               MS. LUDWIG:  Just what I said I think the  
5       last time, just a reminder that we have the same issue  
6       in perennial crops.  You can't rotate.  They're kind  
7       of a little stationary.  So, as you're thinking about  
8       things, keep that in mind.

9               Then I do think, and this is beyond EPA's  
10       scope, but as has been alluded to, the issue is how do  
11       you get growers to change when at the end of the day,  
12       they're going to go with what's most effective and/or  
13       what's cheapest.

14               In the almond industry, for us on  
15       fungicides, we've been drumming in rotate on  
16       herbicides.  There are a limited number of tools that  
17       work against certain weeds.  So, you kind of go back  
18       to them.

19               So, it is a more complicated issue.  I think  
20       EPA is trying to do what they can from their  
21       perspective, but this is an issue that at least the ag  
22       groups have all been struggling with for quite some  
23       time.  How do we get growers to rotate when at the end  
24       of the day whatever works well is going to be the  
25       first choice.  So, we have to continue to educate on



1       that.

2               MR. JONES:  If I could just respond to that  
3       quickly, one of the things that the grower groups can  
4       do is to reach out to the societies, to the entomology  
5       and phytopathology and science societies and try to  
6       make that connection.

7               We find that when we have the three  
8       different groups talking together, the wheat  
9       scientists, and the entomologists, and the plant  
10      pathologists that a lot of times there some  
11      connections that wouldn't be made otherwise.  So, I  
12      would encourage the growers to reach out to the  
13      societies as well to help complete the loop.

14              MR. KEIGWIN:  Ray.

15              MR. MCALLISTER:  Just a couple of quick  
16      questions.  What are the next steps for the PR notice  
17      on herbicide resistance?

18              MR. JONES:  The comments have been  
19      incorporated.  It's in final review now.  It should be  
20      coming out this summer some time.

21              MR. MCALLISTER:  Will there be an  
22      opportunity to see another final draft?

23              MR. JONES:  Well, it's going through its  
24      final review right now.  We've done the public  
25      outreach and the public comments.  So, I don't think

1 it's scheduled for another review before it goes out.

2 MR. KEIGWIN: Cynthia.

3 MR. PALMER: So, echoing Steve Coy on  
4 prophylactic uses, I think it is a challenge with so  
5 many fungicides and insecticides built in the seed  
6 coatings. To recommend scouting or other best  
7 management practices sometimes the growers don't have  
8 that choice of simply scouting and then planting  
9 different seeds, because it's coated on to the seeds.

10 So, I'm wondering to what extent you're  
11 working with the seed industry to make available seeds  
12 for all the different crops that actually do not  
13 contain the fungicides and insecticides.

14 MR. MALLAMPALLI: That's an interesting  
15 thing to consider in the future. We're not working  
16 with the seed industry on this issue, as far as I  
17 know. The scope of the labeling PRN, I think both  
18 PRNs, is really intended to cover conventionally-  
19 applied pesticides sprayed, or genetically-modified  
20 herbicide tolerance crops would be covered as well, by the  
21 herbicide PRN. The seed coating issue is definitely a  
22 legitimate concern, I think.

23 MR. JONES: We did -- and that question has  
24 been raised about the seed coatings and resistance.  
25 We did talk to the insecticide resistance action

1 committee about that. We've also done some work. We  
2 can't find any direct relationships from the  
3 resistance side for some of the seed treatments that,  
4 for example, might be followed up by foliar treatment  
5 earlier on in the season.

6 But we are not working with the seed  
7 industry on that. I mean, we're considering this and  
8 we're considering resistance in a risk benefit  
9 framework because we're going through registration  
10 review and, when appropriate, we think in the new  
11 chemicals as well, new active ingredients.

12 MR. KEIGWIN: Okay, thanks. So, the last  
13 two topics, Anita Pease and Marietta Echeverria will  
14 lead us through those two discussions.

15 MS. ECHEVERRIA: Good afternoon, my name is  
16 Marietta Echeverria. I'm the director of the  
17 Environmental Fate and Effects Division. So, we are going  
18 to briefly go through two updates. We provided  
19 information in the packet. So, the first topic is around  
20 mixture toxicity or a.k.a. synergy.

21 So, this issue became prominent about a year  
22 and a half ago when we discovered that there were  
23 claims being made to the patent and trade office that  
24 chemicals in combination that we were considering for  
25 registration, the companies were making claims of

1 synergy.

2 We have had a longstanding practice in the  
3 program to evaluate single active ingredients in terms  
4 of our risk assessments. The reason being is based on  
5 the information that we have, actual synergistic  
6 interactions. They're actually a really rare  
7 occurrence based on the way that we regulate  
8 pesticides.

9 However, since these claims were being made,  
10 we felt that it was appropriate to consider the  
11 information and to determine whether or not it was a  
12 source of information that was relevant for risk  
13 assessment.

14 So, we've been piloting a process that walks  
15 us through a screening process to determine whether or  
16 not information supporting those claims is actually  
17 relevant for risk assessment purposes. To the extent  
18 that there is relevant information for risk assessment  
19 purposes, we have asked companies to report that  
20 information to us. Then we've gone through and we've  
21 actually evaluated that.

22 So, to date, we can report that we've looked  
23 at approximately eight cases on this issue. For the  
24 majority of cases, what we found is that those data  
25 are actually of little value in terms of risk

1     assessment.  So, in the majority of cases, there's  
2     actually little underlying information that would  
3     actually make it into a risk assessment.

4             There's actually two cases where we saw  
5     potential relevance with respect to the information.  In  
6     those two cases, we made a determination it was most  
7     appropriate to use our guideline testing methodologies  
8     to go to direct formulation toxicity testing.  That  
9     does provide relevant information for risk assessment.

10            So, our goal is to continue piloting this  
11    process through the registration program and as we learn  
12    and we get a number of cases under our belt to  
13    actually make some recommendations and come out with a  
14    white paper and position in terms of the value of this  
15    data from a risk assessment perspective.

16            So, with that, I think we'll open it up for  
17    questions.

18            MR. KEIGWIN:  Steven, then Nichelle, then  
19    Jake.  Cynthia, I don't know if your card is up or  
20    not.

21            MR. COY:  First clarify for me.  These eight  
22    cases of synergy, were they cases that registrants  
23    claimed synergy for their product between different  
24    ingredients?

25            MS. ECHEVERRIA:  Correct.  So, they were

1 actual cases that we were reviewing applications under  
2 registration. We searched patent and trade office  
3 information and they were making those claims. So,  
4 there was a direct need to actually evaluate whether  
5 those claims and the data supporting those claims were  
6 relevant for risk assessment purposes.

7 MR. COY: Okay. So, this is not related to  
8 what the beekeepers usually bring up, synergy from  
9 tank mixes of two separate products?

10 MS. ECHEVERRIA: Correct. So, this was  
11 specifically where we had this source of information  
12 where these specific claims were being made. But this  
13 pilot does not address the tank mix situation that  
14 you're referring to.

15 MR. COY: Okay. And then, at the meeting in  
16 January, there was a presentation that indicated that  
17 at least one -- I don't know what the company was.  
18 But they were using an active ingredient of one  
19 product as a component of a separate product for the  
20 synergism thing. So, that's kind of what you're  
21 talking about in your initial eight cases?

22 MS. ECHEVERRIA: I'm not sure I understand.  
23 Can you repeat?

24 MR. COY: So, they were using -- I can't  
25 remember the product name. A researcher was doing

1 research and he said that an active ingredient for one  
2 product was an ingredient in another formulation. The  
3 reason they put that ingredient in there was a  
4 synergistic effect.

5 MS. ECHEVERRIA: Okay. So, I think that's a  
6 different scenario what you're talking about. There  
7 are some products where an ingredient is designed to  
8 be a synergist. In those cases, we understand how the  
9 synergist works purposefully to enhance efficacy of  
10 the product. So, I'm guessing that's what you're  
11 referring to.

12 But in these cases, there are actually  
13 claims being made to the trade office that said in  
14 combination two separate active ingredients, you would  
15 have enhanced yield or a better effect in the field.

16 MR. COY: Okay.

17 MR. KEIGWIN: Nichelle, then Jake, then  
18 Robyn.

19 MS. HARRIOTT: So, my question is similar to  
20 Steven's. So, the Agency is only evaluating synergy  
21 if there is an explicit claim being made, correct?

22 MS. ECHEVERRIA: Correct, for this pilot  
23 process. In these cases, we felt compelled that there  
24 is an actual claim out there that we needed to  
25 investigate, whether or not there is actual data

1 relevant for risk assessment that would actually  
2 change our risk assessment meaningfully.

3 MS. HARRIOTT: So, you mentioned that is a  
4 pilot. But in the future, will the Agency look at  
5 formulations that have more than one active ingredient  
6 for synergy as part of its risk assessment?

7 MS. ECHEVERRIA: So, for a product that is  
8 co-formulated, we do get formulation specific  
9 information, a typical end-use product when the  
10 application is made directly to water. So, we  
11 consider and we evaluate that information as part of  
12 the risk assessment currently.

13 MS. HARRIOTT: But it's not throughout the  
14 program? You said it's only for those applied to  
15 water.

16 MS. ECHEVERRIA: And also for plant toxicity.  
17 It's based on the formulation specific information.  
18 Also, field testing for pollinators is also  
19 formulation specific.

20 MS. HARRIOTT: Okay. So, the eight cases  
21 that you mentioned, so there are currently eight  
22 formulations out there that claim synergy on their  
23 labels?

24 MS. ECHEVERRIA: So, there were eight active  
25 ingredients that there was an application process for



1     which they were making claims to the patent office  
2     that we've run through our relevancy criteria and  
3     we've evaluated whether or not there was information  
4     to change our risk assessment.

5             So, it's not formulation specific here. So,  
6     it's an active ingredient A and maybe the company who  
7     has active ingredient A, or another company we've  
8     actually found out, and they're actually making claims  
9     in combination with another active ingredient in terms  
10    of a tank mix or some kind of use together, you would  
11    get enhanced yield or enhanced efficacy.

12            MR. KEIGWIN: Jake, then Robyn, then Sharon.

13            MR. VUKICH: You had mentioned that there's  
14    a process for screening and searching the patent  
15    office claims. Is that process available? Is it an  
16    SOP or is that something that we can see?

17            MS. ECHEVERRIA: Yes. It's a draft process  
18    that's available upon request. We have been giving  
19    out guidance as we've developed the process and  
20    learned as we've gone. So, we're happy to share that  
21    information. It is draft.

22            MR. KEIGWIN: Robyn, then Sharon, then  
23    Richard.

24            MS. GILDEN: So, could you just clarify for  
25    me. With the eight cases, you said most of them

1 weren't applicable because of a variety of different  
2 reasons. So, the data wasn't good or it was negative  
3 or it was missing? What made them not be usable  
4 except for the two cases?

5 MS. ECHEVERRIA: So, in some cases, there  
6 were no relevant data actually supporting the claim.  
7 In other cases, it was actually limited information.  
8 Then, in other cases, there was actually information  
9 but it was not robust enough to support a statistical  
10 analysis to support the claim. So, there's more than  
11 one sort of outcome.

12 MS. GILDEN: So, would that mean that where  
13 there was missing data or not good quality data, would  
14 you go back to those companies and say we need more  
15 data or better data?

16 MS. ECHEVERRIA: So, we weren't piloting this  
17 to impose additional data requirements. We were using  
18 best available information, as is our practice. So,  
19 if there was a data source that had the best available  
20 information there was evidence in that data source, we  
21 would want to use it. But we're not looking to expand  
22 requirements in absence of those data.

23 MR. KEIGWIN: Sharon, then Richard, then  
24 Cynthia, and I think Lori Ann, your card is up.

25 MS. SELVAGGIO: I've got a question about

1     this.  Bullet number two refers to USGS ambient water  
2     quality data.  It says in a predominant number of  
3     cases, the potential toxic risk is dominated by one to  
4     a few chemicals.  That phrasing is a little odd to me,  
5     potential toxic risk.  As you know, depending upon the  
6     watershed, highly agricultural or highly urbanized  
7     watersheds can very, very commonly have multiple  
8     pesticides detected in a single sample.

9             So, I'm wondering what else is EPA doing?  
10    It is common that you see mixtures that are often  
11    dominated by a few key chemicals.  So, what else is  
12    EPA doing to evaluate the synergistic interaction, the  
13    potential for synergy amongst those frequently used  
14    pesticides that commonly show up in aquatic systems?

15            MS. ECHEVERRIA:  So, for this pilot, we're  
16    evaluating the patent and trade information, patent  
17    and trade office information.  To the extent that  
18    there is open literature data with respect to an  
19    active ingredient that is robust enough for us to  
20    consider for risk assessments, we do that as part of  
21    our re-evaluation process.

22            MR. KEIGWIN:  We'll just take these last  
23    three because we still have one more topic and then  
24    the break.  So, Richard, then Cynthia, then Lori Ann.

25            MR. GRAGG:  Thank you.  I think I just

1     understood what you were saying. So, if a company is  
2     claiming an interaction in effect to enhance the  
3     pesticide, then you're concerned that that could be  
4     tox interaction in terms of health. So, therefore,  
5     you're going to investigate it?

6             MS. ECHEVERRIA: Correct.

7             MR. GRAGG: Okay. So, are you using any of  
8     the 6-pack assessment to evaluate the potential?

9             MS. ECHEVERRIA: So, we considered that  
10    information from an ecological perspective to non-  
11    target mammals. This is in the context of ecological  
12    risk assessment. I should have clarified that. So,  
13    we are generally looking at non-target insects like  
14    the pollinators, birds, aquatic invertebrates, fish,  
15    and plants. Non-target plants has been a big one.  
16    So, it's really in the context of that kind of  
17    evaluation.

18            MR. GRAGG: Thank you.

19            MR. KEIGWIN: Cynthia.

20            MS. PALMER: I just have a clarifying  
21    question. I'm sure I just somehow missed the answer.  
22    So, on page one, it says a large number of U.S. patents  
23    have claims of interactions. Then, on page 2 we learn  
24    about these eight cases that you looked at in more  
25    depth.

1 I'm just wondering was eight the total  
2 universe of claims for which there is sufficient data  
3 or if not, how did you choose to focus on those eight?

4 MS. ECHEVERRIA: So, the eight had to do with  
5 applications that were in front of us for regulatory  
6 decision making. So, that's why we focused on the  
7 eight. We were actively working on those risk  
8 assessments in support of a registration decision.  
9 But there is this other body of information out there  
10 that has not been looked at systematically.

11 MR. KEIGWIN: And Lori Ann.

12 MS. BURD: Last July, we, at the Center for  
13 Biological Diversity, put out a report where we looked  
14 into the past six years of pesticide product approvals  
15 by four companies in the past six years. We found  
16 that 96 out of the 140 had pesticide patent  
17 applications for them.

18 Then we followed that up with a petition,  
19 because we found that going back to 2007, there was a  
20 regulation requiring pesticide registrants to submit  
21 that information. Then a regulation was removed. I  
22 think it was called unnecessary. So, we are still  
23 awaiting a response to that petition and eagerly look  
24 forward to it.

25 MS. ECHEVERRIA: So, as I mentioned, we are

1 in receipt of the petition, and we are working on the  
2 response right now.

3 MS. BURD: For folks that are interested,  
4 that report again is called Toxic Concoctions. It  
5 contains tables of pesticides we looked at.

6 MR. KEIGWIN: Okay, we'll do one more and  
7 then take a break. Maybe it will go quick. ESA. Not  
8 because it's yours, Anita.

9 MS. PEASE: Hi, everyone. I'm Anita Pease.  
10 I'm the assistant director of the Environmental Fate  
11 and Effects Division. Saving the best for last, I  
12 guess.

13 So, you've got your one-pager. So, I know a  
14 lot of you, this is a topic that is near and dear to  
15 your heart. For the past four years, we have been  
16 working with the Services, U.S. Fish and Wildlife  
17 Service, National Marine Fisheries, to implement the  
18 recommendations from the National Academy of Science  
19 Report that came out in 2013 to develop a common  
20 method for evaluating the risk of pesticides to  
21 endangered species.

22 We developed an interim method back in  
23 November of 2013. We agreed then that we were going  
24 to apply that method to five chemicals.  
25 Chlorpyrifos, diazinon, and malathion is the first

1 three. And then carbaryl and methomyl is the next  
2 two. We were going to do that in the context of  
3 nationwide biological evaluations, so the first ever  
4 nationwide consultations for endangered species based  
5 on pesticides.

6 Back in April of 2016, we released the first  
7 draft biological evaluations for the first three  
8 chemicals, which are chlorpyrifos, diazinon, and  
9 malathion. We sent those out for a 60-day public  
10 comment period. We received a lot of public comments.  
11 We got about 70,000 comments, most of which were a  
12 letter writing campaign to ban those chemicals. I  
13 think we had about 120 substantive comments mostly  
14 from grower groups, pesticide industry, and such.

15 After we received those comment letters, we  
16 had a stakeholder meeting in June of 2016, a two-day  
17 stakeholder workshop, where we got a lot of good  
18 recommendations on some of the challenging issues  
19 related to aquatic modeling, a weight of evidence  
20 approach, and seeking recommendations on further  
21 refinements, both spatially and nonspatially, to our  
22 risk assessments.

23 So, recently, in January of 2017, we did  
24 release the final biological evaluations, along with a  
25 response to comment document. It became necessary

1 because of our consultation deadlines, our court-  
2 mandated deadlines for the first three chemicals final  
3 biological opinions, which is the next document in the  
4 process. Those are due January of this year, 2017,  
5 for the first three chemicals.

6 It became necessary to bin all the  
7 recommendations that we received into those that we  
8 felt we could implement in the short term and those  
9 that would take longer to develop, having those  
10 discussions with the Services so we could come to  
11 agreement.

12 So, we released the final BEs, acknowledging  
13 that not all of the public comments that we had  
14 received we would have time to address. So, we did  
15 what we could in terms of addressing errors, working  
16 on some improved transparency for our modeling, adding  
17 and deleting species as appropriate, and also making  
18 some changes to our aquatic modeling approach to  
19 include some further refinements. So, those documents  
20 are now available.

21 Also, in mid-April, we received a letter  
22 from the registrants for the three chemicals, for  
23 Chlorpyrophos, diazinon, and malathion, basically  
24 making three requests to the Agency. The first  
25 request was they wanted us to retract the final BEs



1 for the first three chemicals, they want the Services  
2 to stop work on biological opinions, the next step in  
3 the process, and also for us to go back to the courts  
4 and request an extension on the court-mandated  
5 deadlines for the final biological opinions to allow  
6 us all more time to integrate all the comments that  
7 we've received.

8 Also, EPA has completed draft BEs for  
9 carbaryl and methomyl. Those have not yet been  
10 released for public comment yet. That's all tied up  
11 in consideration of the letter that we got from  
12 industry. I'll also mention that in addition to the  
13 industry letter, we received some letters of support  
14 from Crop Life America, from Rise, and also from the  
15 registrants for carbaryl, basically voicing support  
16 for the industry letter.

17 So, right now we continue to work with the  
18 Services on develop further refining the methods and  
19 also working on methods for step 3, which are the  
20 biological opinions. We're expecting that the  
21 Services will release biops, draft biops for the three  
22 chemicals in the beginning of the summer.

23 So, with that, I'll stop and take any  
24 questions.

25 MR. KEIGWIN: Okay, Robyn.

1 MS. GILDEN: So, thank you very much for  
2 that quick update. After you're done with all of  
3 these pesticides, what pesticides are you going to  
4 target next?

5 MS. PEASE: So, next on the docket after  
6 these five are four herbicides. That's atrazine,  
7 simazine, propazine, and glyphosate. Right now, the  
8 commitments are for EPA to complete BEs by 2020 and  
9 for the Fish and Wildlife Service to complete the biop  
10 by 2022.

11 MR. KEIGWIN: Richard, then, Sharon, then  
12 Lori Ann.

13 MR. GRAGG: So, are the industry groups  
14 asking you to go back and redo what you've already  
15 done or approach it in a different way?

16 MS. PEASE: Yes. So, basically what industry  
17 is asking is that we go back and we refine the first  
18 two steps in the process, which are EPA's biological  
19 evaluations. So, if you're not familiar, the final BEs  
20 that came out had a large number of likely to  
21 adversely affect determinations. About 97 percent of  
22 the species for chlorpyrifos and malathion moved on  
23 to the biop as needing further evaluation by the  
24 Services. For diazinon we had about 80 percent of the  
25 species.

1           So, it's basically going back to the methods  
2   that we developed and including further refinements  
3   with exposure, the way we evaluate exposure, the way  
4   we characterize toxicity, and also how we evaluate  
5   geospatially the areas where pesticide use overlaps  
6   with areas where species occur on landscape. So,  
7   there were a lot of different recommendations.

8           MR. GRAGG: So, these were the methods  
9   they're wanting you to revisit?

10          MS. PEASE: Yes.

11          MR. GRAGG: Are these standard EPA methods?

12          MS. PEASE: They're new methods. They're new  
13   risk assessment methods. They make use of our  
14   existing ecological risk assessment framework, but we  
15   did develop a lot of new tools. We have a lot of new  
16   methods that we use in these BEs that we have not  
17   typically used in our normal FIFRA assessments.

18          MR. GRAGG: So, in what you have now and if  
19   you revisit it, when you revisit it, what implications  
20   will that have for human health risk assessments on  
21   these pesticides?

22          MS. PEASE: This is specific for --

23          MR. GRAGG: Yes, I know. I know, endangered  
24   species. I'm saying if you go back and revisit it for  
25   the endangered species, are there any implications for

1 the human health risk assessment?

2 MS. PEASE: Not that I'm aware of.

3 MR. GRAGG: Okay.

4 MR. KEIGWIN: Sharon, then Lori Ann, then  
5 Marc.

6 MS. SELVAGGIO: Thanks for all your work on  
7 this so far. I know these documents and this process  
8 is extremely time consuming and laborious. It  
9 addresses some big questions, though, which are what  
10 effects do pesticides have on the most vulnerable  
11 species in the nation, which is kind of similar to the  
12 question that we're asking when we talk about  
13 vulnerable people, such as farmworkers and children  
14 and those who are occupationally exposed.

15 It's really important that we consider the  
16 particulars of listed species when we look at  
17 pesticides through the process. So, I'm glad, even  
18 though I've only been working on this for two years,  
19 this whole process has actually been kind of underway,  
20 as you guys know, for over a decade.

21 I think it seems late in the game to get  
22 this kind of recommendation, because in the two-and-a-  
23 half years that I've been kind of paying attention to  
24 this, I think you guys have held at least four  
25 stakeholder workshops outlining your methods. It's

1       been open to the public.

2               So, I know that you've done a lot of work to  
3       try to make sure that the assumptions and the models  
4       and the scientific processes that underlie ultimately  
5       the conclusions are transparent and available to people  
6       to understand in advance. So, I appreciate that you  
7       have gone to that effort. I just think it's late in  
8       the game for a request like this.

9               When I look at the three requests, I guess  
10       my question for EPA is, since this first two batches  
11       are basically under settlement agreement, if you can't  
12       get a modification of the settlement agreement,  
13       doesn't that make moot the first two requests?

14              MS. PEASE: Yes, that's a good point.

15              MS. SELVAGGIO: Okay. I just wanted to see  
16       if there was something I was missing. So, thanks.

17              MR. KEIGWIN: Lori Ann, then Marc, then  
18       Dawn.

19              MS. BURD: I'm going to echo a lot of what  
20       Sharon just said. The contents of at least the first  
21       letter -- I haven't seen Crop Life's or the other ones  
22       that you mentioned. The contents of these letters are  
23       all rehashing points that have been made in the  
24       multiple comment periods and the multiple public  
25       meetings.

1           This has been the most transparent  
2       consultation process in history with these long  
3       comment periods and many opportunities for stakeholder  
4       input. It's incredibly frustrating to see this Agency  
5       considering an 11th hour attempt to thwart a nearly  
6       half decade of progress on this.

7           The Center for Biological Diversity strongly  
8       encourages you to not grant this request.

9           MR. KEIGWIN: Marc and then Dawn.

10          MR. LAME: So, this was a fairly predictable  
11       game of delay that registrants and the associations  
12       play. They've kind of always done this, at the same  
13       time asking for sound science and transparency, which,  
14       again, I agree has been outstanding in this case.

15          I guess my question is, do you have an  
16       estimate of how many species will be going extinct in  
17       the United States before we get to do this again?

18          MS. PEASE: I don't have an answer to that.  
19       I think it depends on what their current baseline status  
20       is right now. Some species are recovering quite well  
21       that aren't still on the list. I look to Gina to  
22       clarify this, but others are in decline. So, there  
23       are some that are on the brink. These are criteria  
24       that are being considered in the biological opinion  
25       right now. Are the species trending up or down, and

1       that's part of the equation. But I can't even fathom  
2       a guess the answer to that question.

3               MS. SHULTZ: So, you're asking an open-ended  
4       question like what would the delay be. So, I can't  
5       tell you if there were a delay, how long it would be  
6       and how many species would go extinct during that time  
7       due to any of the pesticides that we're consulting on  
8       or other reasons unrelated to pesticides.

9               MR. KEIGWIN: Dawn, then Ray, then Gabrielle.

10              MS. GOUGE: Given that you're intimately  
11       aware as an expert team of the process that you've  
12       been through, if you were to go back, modify your  
13       process, and move forward, would you anticipate any  
14       different results at the end of the process?

15              MS. PEASE: I think we would. I think we  
16       would have a smaller number of likely to adversely  
17       affect determinations for species. I think some of  
18       the streamlining steps that we're considering right  
19       now, some of the recommendations from stakeholders,  
20       both registrants and grower groups, we agree with and  
21       we think those are good recommendations. We would  
22       like to implement them given the time to do so.

23              So, I expect that we would probably have a  
24       fewer number of species that would move forward in  
25       step 3, which is the Services biological opinion. We

1 want to be protective. We're not interested in just  
2 reducing numbers. We're interested in focusing our  
3 resources on a species that actually need and deserve  
4 protection.

5 When everything shoots through to the next  
6 level, that's not a very good screen. So, I think we  
7 acknowledge that. So, I think yes, we would expect  
8 different conclusions.

9 MR. KEIGWIN: Ray, then --

10 MS. ECHEVERRIA: Can I add one thing?  
11 One point I would make, I agree, we might expect  
12 different conclusions with respect to the step one and  
13 step two conclusions. But I don't know that we could  
14 say whether it would make an actual difference in  
15 terms of the biological opinions, which ones we  
16 determine are in jeopardy or not in jeopardy, or the  
17 regulatory RPAs are measured that we'd actually put in  
18 place. I don't know that we have that information. I  
19 do think it would make a difference in terms of our  
20 resources in terms of how big the consultation is to  
21 begin with.

22 MS. SHULTZ: So, I can confirm that  
23 as well. So, as we're drafting the biological  
24 opinion, there are species that were determined to  
25 have a likely to adversely affect. And after we've



1     done our step three review, we've concluded that  
2     actually they're not likely to adversely affect. So,  
3     we're not carrying it all the way through the jeopardy  
4     analysis.

5             But that's one of the many, many  
6     streamlining things we've talked about for the future  
7     consultations. It will be much more efficient if EPA  
8     uses that same bar that we've used in step three for  
9     not likely to adversely affect and then the  
10    consultation concludes at the BE stage.

11            MR. KEIGWIN: Ray and then Gabrielle.

12            MR. MCALLISTER: I think Anita made the  
13    point I wanted to make, basically. It's my  
14    understanding that the biological evaluations found  
15    some 87 percent of the species in the likely to  
16    adversely affect category, which doesn't bear any  
17    relationship with what we see in the field. These  
18    products have been used for decades and don't see  
19    declines in those species. So, I think it's  
20    worthwhile to reevaluate.

21            MS. PEASE: Yes, I just want to make a point.  
22    So, the effects are effects to one individual. So, I  
23    think that's important to note. That's what LAA  
24    means. It's not the population; it's at the  
25    individual level.

1 MR. KEIGWIN: Gabrielle.

2 MS. LUDWIG: From the grower groups'  
3 perspective, I've looked at the draft biological BE  
4 evaluation. I just want to say for those of you who  
5 say okay, this is all finished science, it really  
6 isn't. There's a lot of new stuff here. I don't  
7 claim to grasp all of it, but I will say that from our  
8 perspective, one of the issues really is --

9 I understand the reasons why, but some of  
10 the assumptions on how the products are used are  
11 absolutely worse, worse, worse case scenario. It  
12 would be nice if you not only had what I call the  
13 worse, worse --

14 I mean, some maximum label rates are like  
15 seven times what we actually use in the field, but  
16 also something where you looked at what I call a  
17 maximum normal use rate. So, you could really see how  
18 far off are we from things or where can we make some  
19 adjustments and maybe make some changes earlier on.

20 But I just want to be clear that this is  
21 really complicated. Having legal deadlines that short  
22 change the process and the public process for  
23 discussion about it really is frustrating. Again,  
24 it's not saying it's all going to end up one way or  
25 the other; it's just these things take time to try it

1 out, figure out what works and doesn't work.

2 I come back to having had the chance to  
3 observe EPA go through this process on the dietary  
4 risk assessment, on the human dietary risk assessment  
5 back when the Food Quality Protection Act got passed.  
6 Those first human health risk assessment showed  
7 substantial risk, actually for some of the exact same  
8 compounds we're talking about now.

9 When those risk assessments were made  
10 publicly available and grower groups could look at  
11 them and say no, that's not how we're using it, we're  
12 using it this and this way, and plus some other  
13 refinements in the risk assessment methodology going  
14 to a probabilistic methodology, using pesticide data  
15 program residue data, you ended up with a sense that  
16 okay, now we're dealing with the risks that really are  
17 of concern. Beforehand, everyone was like okay, this  
18 just doesn't make sense, as Anita was sort of saying,  
19 when you have everything being a problem, when it  
20 doesn't ring true.

21 So, I just want to say I realize there's a  
22 lot of different interests here. But from a grower  
23 group's perspective, not wanting to have things all  
24 right or all wrong, this has been frustrating in terms  
25 of having deadlines that didn't allow us to have that

1 really transparent process to move forward. So, I  
2 just want to say I don't think things are as settled  
3 as they seem to be.

4 But this has been a learning process. I  
5 mean, I do think EPA had to try this for better or for  
6 worse to find out what it takes to do every species  
7 between Maine and the Mariana Islands and barely  
8 survive it. Anyway, I just want to say that it's  
9 complicated, hard.

10 So, having the time does make a  
11 difference. Again, I'm not saying it's going to end  
12 up all one way or the other. I think there's  
13 additional information either way that could help  
14 inform this process.

15 MR. KEIGWIN: So, Sharon, you get the last  
16 comment.

17 MS. SELVAGGIO: It's just a question. I  
18 forgot to ask something. On your update sheet, it  
19 says EPA is exploring using species specific toxicity  
20 data earlier in the first step. If my recollection  
21 serves, you used like HCO5 from the species  
22 sensitivity distribution, unless you already had  
23 species specific data, right? I thought you already  
24 used that.

25 MS. PEASE: Yes, we do, but that doesn't come

1     into play until step two. If you recall, step one is  
2     the no effect/may effect call. That's right now only  
3     on geospatial co-occurrence. So, there's no toxicity  
4     information that's included in that step right now,  
5     other than the off-field transport part of it.

6             MS. SELVAGGIO: Okay, thanks.

7             MR. KEIGWIN: So, we're running about 15  
8     minutes behind. Arnold has already set his timer for  
9     his talk, which isn't for like a half an hour or more.  
10    So, why don't we try to gather back here at 3:25. It  
11    gives you about 15 minutes. Thanks.

12                     (Whereupon, a brief recess  
13                     was taken.)

14            MS. MOSBY: -- and Melissa Panger  
15    who have been the co-chairs who have helped  
16    to facilitate and just get all of the information that  
17    we needed and advice we needed from the workgroup.

18            So, I'd like to just start with  
19    talking about -- just to refresh everyone's memory  
20    about the OPP goal, and just to mention that many of  
21    you remember that we started this workgroup, the PPDC  
22    incident workgroup, 18 months ago. The goal of the  
23    workgroup was to develop an electronic incident data  
24    system that is publicly available and useful to a  
25    broad stakeholder group. So, that was the goal of the

1       workgroup. We wanted to receive advice from the PPDC  
2       workgroup on this.

3               So, we set out to develop a new system to  
4       one, address the deficiencies in our current system.  
5       So, that meant that we were looking to have a system  
6       that would improve reporting by making reporting  
7       easier for both voluntary and for required incident  
8       reports, obtaining more and higher quality incidents  
9       for risk assessments, improving consistency in our  
10      reporting, also to enhance efficiencies by eliminating  
11      manual data entry, reducing time that we spent on FOIA  
12      requests, and also we wanted a system that would  
13      support quality science-based decision making, and  
14      also we wanted a system that would encourage data  
15      sharing within EPA and between other agencies and  
16      stakeholders. So, we were trying to solve a problem.

17             The problem I kind of stated in going  
18      through what we wanted, but the problem was that we  
19      had primarily flat files, no data. We have manual  
20      data entry. We have inconsistent information, missing  
21      information. Our data is submitted in various parts  
22      of the organization and also submitted in various  
23      forms. It doesn't talk to other systems.

24             So, the current charge that we had for the  
25      PPDC incident workgroup was to advise us on which data

1 might go into this new data system and to get input  
2 for system development. It's worth noting that the  
3 charge has evolved over time. We started out with  
4 sort of a start and finish, and we would have had  
5 substantial down time during system development.

6 Our current thinking is that the PPDC  
7 workgroup would help us on the front end, which is the  
8 data elements, and then we would go off and start  
9 working on system development. Then we will reconvene  
10 on the implementation issue. So, that's the approach  
11 that we are using.

12 The workgroup has been providing advice on  
13 what data might go into the system. So, that includes  
14 data elements, the number of data elements, also the  
15 thought of maybe we need a smaller number of elements  
16 for certain kinds of incidents. We talked about a  
17 trade-off between the cost and the benefit of  
18 additional data elements and when might some data  
19 elements apply. Yesterday, we had a facilitated  
20 meeting with the workgroup to talk more about this  
21 issue of when would certain data elements apply.

22 What we were trying to get at were some  
23 questions like should we strive to get all the data  
24 elements for every incident? What are the  
25 circumstances where we would strive to get all the

1 data elements? So, we got input on questions like  
2 that, just trying to figure out when do all of these  
3 data elements apply, what type of incident would they  
4 apply for.

5 So, we got that input. Then, the other part  
6 of our charge was input for system development. We  
7 wanted to hear from the workgroup on parallel  
8 databases. So, we talked about other systems that  
9 might help us in designing or thinking about what our  
10 system would look like.

11 Rather than to have the group be dormant for  
12 some time, we decided to dissolve the workgroup and  
13 come back to the PPDC for further input prior to  
14 implementing a new system. So, as I said, we received  
15 input on a host of data elements. I went through  
16 those.

17 We've got some work, and we've received just  
18 excellent advice and input that we'll take into  
19 consideration. But we need to go back now and look at  
20 the data elements that we have and then we would come  
21 back and start a new workgroup.

22 But what we would do in the future with the  
23 PPDC would be sort of implementation issues. It would  
24 be verifying and validating incident data in the  
25 database, protecting issues -- these are issues that



1     came up on implementation that we haven't come to some  
2     conclusion about -- protecting certain information,  
3     PII, and screening data for public release.

4             So, these are issues that we still have to  
5     address. Those are those implementation issues. So,  
6     we're at a place where we have received the advice for  
7     our initial charge, and we would like to, as I said,  
8     dissolve the workgroup and get back with you through  
9     another workgroup. We'll figure out the process for  
10    doing that.

11            I want to just thank the workgroup. You  
12    have provided invaluable input. We've got diverse  
13    input from a diverse group of stakeholders. As I  
14    said, your input has been invaluable. OPP appreciates  
15    the feedback already received by the PPDC workgroup.  
16    We look forward to taking your input under  
17    consideration as we move forward.

18            MR. KEIGWIN: Thanks, Jackie.

19            MS. MOSBY: You're welcome.

20            MR. KEIGWIN: If there are one or two  
21    questions or comments, we can take those. Cheryl and  
22    Liza.

23            MS. CLEVELAND: So, I appreciate being able  
24    to be part of this workgroup. I guess I really  
25    struggle with this constant discussion of data

1 elements for data elements sake without having broader  
2 context. Personally, I just struggle with it, so it  
3 was hard.

4 They'd say rank this or when do you need  
5 this. I'm like well, how are you getting this data?  
6 Is it coming from a public call? Is it coming from a  
7 search of another database? Is it coming from an EPA  
8 staffer that's going to backfill this? It was very  
9 difficult. I tried really hard to continue to stay  
10 focused on this.

11 That's what I just want to say. I think you  
12 did push through. We had a long list of data  
13 elements. But I think you need to consider them to be  
14 a little bit draft. Even in the car yesterday, there  
15 were some people discussing these data elements as if  
16 they would be somebody on the phone, taking a  
17 complaint call at a call center. And there were other  
18 people thinking no, it's a state investigation person  
19 that's following up on this. So, it's not clear how  
20 you're collecting, who is getting it.

21 We heard real clear that if you're talking  
22 to the public on the call, you'd only have a short  
23 amount of time, 6 to maybe 11 minutes keeping somebody  
24 on a call. That's it. So, if you want to push to get  
25 all these data elements filled, that's going to be

1       very difficult.

2               So, these other questions about when do you  
3       strive to get everything. That's a question. How  
4       much resource do you want to put into backfilling?  
5       How much EPA resource or other state regulatory  
6       resource do you want to put on to backfill things that  
7       you don't get the first time?

8               So, I would say we did bring forward some  
9       concerns last year where we stated that without  
10      context, some of this is very difficult. Mandatory  
11      versus voluntary, the data collection mechanism  
12      itself, the implications for a registrant 6(a)2  
13      information, and then the verification and validation  
14      part of this.

15              We were only talking one part of the  
16      project. So, you had to start somewhere. Great.  
17      Consider them draft until you can answer some of  
18      those other questions. Thank you.

19              MS. MOSBY: Thank you.

20              MR. KEIGWIN: Liza and then Amy.

21              MS. FLEESON TROSSBACH: I think part of my  
22      question got answered by Cheryl, but just for my  
23      clarification, just to refresh my memory, this would  
24      be any type of incident? So, it could be a possible  
25      pesticide misuse or alleged adverse effects to

1 pollinators from pesticides. So, this could be any  
2 type of incident that involved pollinators?

3 MS. MOSBY: Yes.

4 MS. FLEESON TROSSBACH: Also, the report  
5 could come from anybody. So, the general public,  
6 state-lead agency, or registrant, any of those  
7 different groups?

8 MS. MOSBY: Yes.

9 MS. FLEESON TROSSBACH: So, I would just  
10 like to reiterate what Cheryl indicated, the concerns  
11 of state lead agencies, for example, in our business.  
12 We get a lot of complaints, a lot of tips,  
13 Complaints, and reports often have no pesticide related  
14 issue at all.

15 So, one of the concerns is that if that's  
16 reported as an incident, is it really an incident?  
17 There's not a finding of some type of violation or an  
18 actual adverse effect can be -- you know, there's some  
19 sort of causation there.

20 So, I would agree that verification and  
21 validation and then coming full circle. And then also  
22 ensuring that you're not double counting. If the  
23 general public reports it and I as a state-lead agency  
24 report it and somebody else, then you have these  
25 multiple things.

1           So, just to be thinking about in addition to  
2   which data elements are appropriate, how you're going  
3   to gather the data, verifying and validating. Is that  
4   full circle to make sure that you're not getting false  
5   data. Good data in, good data out. The opposite is  
6   true as well. If that's going to be used to inform  
7   decisions, we want to make sure that it's valid data.  
8   So, thank you.

9           MS. MOSBY: Thank you.

10          MR. KEIGWIN: Okay, we'll wrap up with Amy.

11          MS. LIEBMAN: I appreciate all the concerns  
12   that are being raised. I just wanted to say that the  
13   incident workgroup has really worked on a really  
14   important issue. I encourage you to continue the road  
15   that you're going down.

16          Quite frankly, if we're getting like extra  
17   reports, I just think that's great because we're not  
18   getting a lot -- we need to sort of figure out how to  
19   gather incident data. I understand the concern about  
20   possible double counting, but at this point, because  
21   it's so haphazard and there's not a good system in  
22   place, this is a start and a step forward and much  
23   needed.

24          I'll just put my plug that I put in for every  
25   single PPDC meeting, but we really do need a system

1     that's national where we can systematically report  
2     pesticide incidents. I would love to go the  
3     regulatory route on that, but I know that's probably  
4     not going to happen. But this is something that is  
5     greatly needed if we're to understand what's happening  
6     with pesticides once they've been approved.

7             MR. KEIGWIN: Okay, thanks, Jackie, and  
8     thanks to the workgroup that's gotten us to this  
9     point.

10            Now, what Arnold has been waiting for all  
11     day. This time I won't also forget to introduce Yu-  
12     Ting since she's a co-session chair for this one, so  
13     Yu-Ting Guilaran as well from the Pesticide Re-  
14     evaluation Division. And Bob McNally, he wasn't on  
15     the agenda. That one I have an excuse.

16            MR. LAYNE: Good afternoon, everyone. I'm  
17     Arnold Layne, Deputy Director of the Office of  
18     Pesticide Programs. I'm thankful for the opportunity  
19     to give you an update on Zika. I'm going to provide  
20     you, with the help of Yu-Ting, the status of  
21     registration reviews. With the help of Bob, we're  
22     going to talk about integrated pest management. Then,  
23     lastly, I just wanted to let you know that from the  
24     last PPDC meeting, we heard you with respect to your  
25     concerns and desires to bring together a workgroup for

1 public health issues. We'll talk about that.

2 To start with, an overview of Zika for those  
3 of you who weren't here last time. This is such an  
4 important issue. As you see in this slide, the former  
5 CDC director, Tom Frieden, highlighted the critical  
6 nature of Zika in his statement that you can read, as  
7 well as the statement or quote provided from the New  
8 England Journal of Medicine, which says it all, I  
9 think.

10 This next slide really breaks my heart, and  
11 it shows you the impacts of Zika on our most precious  
12 blessings, children. Zika is a public health concern,  
13 and it is a virus that is spread by mosquitoes that is  
14 known to cause birth defects in fetuses infected, and  
15 also Guillain-Barré Syndrome in adults.

16 Zika affects all of us through both health  
17 and emotional tolls that it takes on us, as well as it  
18 costs society. It's imposing. I have heard figures  
19 of up to \$10 million for health care and just support  
20 for babies born with Zika. So, you can imagine the  
21 economics associated with that.

22 EPA is involved in a large and active  
23 federal response to prevent, treat, and gather data on  
24 Zika transmission. The Office of Pesticide Programs  
25 has a key role since we regulate mosquito control

1 pesticides and repellants, as well as advocate. We  
2 really do advocate first for integrated pest  
3 management methods for control.

4 I believe that all of us who work in the  
5 area of pesticides and human health, we must care  
6 deeply about how our expertise and interest can  
7 improve the lives and livelihoods of people by  
8 avoiding disease, protecting human health, and  
9 protecting the environment.

10 This particular slide here shows the number  
11 of Zika cases in the U.S. It is substantial, with most  
12 reported cases in Puerto Rico. While thousands of  
13 Zika virus cases are reported, most have been acquired  
14 through travel.

15 This map shows the spread of Zika across the  
16 U.S., with the darker filled areas showing higher number  
17 of cases. So far, only the Miami-Dade area of Florida  
18 and the Brownsville and border areas of Texas have  
19 confirmed locally acquired cases of Zika. In some  
20 respects, that's good news.

21 This next slide will show you some of the  
22 epi data associated with Zika. So, these numbers are  
23 from the 12th of April. I do have some updated  
24 numbers. I'm not sure that it matters. The fact is  
25 that the numbers are going up.



1           So, in the continental U.S., we're looking at  
2   right now, my latest figures, are 5,264; U.S.  
3   Territories 36,575. Of those 36,000 in the  
4   territories, only 143 of those cases are travel  
5   related. Of those 36,000 cases, 35,400 of those  
6   essentially are in Puerto Rico, 997 in the U.S. Virgin  
7   Islands, and 132 in American Samoa.

8           The pregnancies that have been officially  
9   report in CONUS is 1,762, and U.S. territories is 3,592.  
10   Pregnancy outcomes in the United States, so far there  
11   have been over 1,300 pregnancies that have gone to  
12   completion. Of those, 56 live born babies with Zika  
13   related defects, and there have been 7 pregnancy  
14   losses. Those babies that were lost did in fact have  
15   Zika related defects.

16          If you're wondering about the territories  
17   and the pregnancies, my data comes from CDC. CDC does  
18   not report pregnancy outcomes on the territories  
19   because of the methodology differences and how they're  
20   reported and/or tracked. CDC has a low confidence in  
21   the numbers from the U.S. territories. So, that's why  
22   they don't track those numbers. They are working with  
23   the U.S. territories to have that capacity. It used to  
24   be there and then all of a sudden it changed.

25          So, Zika is a virus that's been known since

1 the 1940s. There was a 2007 outbreak in Micronesia  
2 that resulted in an estimated 900 cases and a  
3 population of less than 8,000 people. Over the past  
4 two years, there's been more than 30,000 suspected  
5 cases of Zika that were reported from the French  
6 Polynesia and other Pacific islands. Just about two  
7 years ago, Zika was identified in Brazil and now in  
8 the Americas there are tens of thousands of known  
9 cases.

10 With insect season soon to start up again,  
11 and some places already have, there's a fair amount of  
12 concern by public health professionals that Zika cases  
13 may increase. We had a very mild winter this past  
14 winter, so we're expecting these numbers to go up.

15 Zika is closely related to dengue, yellow  
16 fever, Japanese encephalitis, and West Nile virus. As  
17 you know, it's primarily transmitted by *Aedes aegypti*  
18 or *albopictus*. The modes of transmission include  
19 intrauterine and perinatal transmission, sexual  
20 transmission, laboratory exposure. I think there's  
21 been one case as far as I'm aware of of lab transmission, and  
22 a number of cases of blood transfusion.

23 So, with the outbreak in Brazil, a  
24 connection was made between pregnancy outcomes and  
25 Zika virus. Subsequent studies have determined the

1     association between the disease and health outcomes,  
2     like microcephaly, brain calcifications, and other  
3     brain abnormalities. There have been sufficient cases  
4     of birth defects associated with Zika that there is  
5     now a condition called Congenital Zika Syndrome. So,  
6     if you hear that terminology, you'll know what it  
7     means.

8             So, this infection has been linked to a  
9     number of things, including eye abnormalities, hearing  
10    loss, limb abnormalities such as club foot, as well as  
11    impaired growth. Most recently, research is ongoing  
12    related to other health consequences that may be  
13    associated with Zika Syndrome, including such things  
14    as epilepsy in these children.

15            The other point I want to make is there are  
16    some babies who are born who appear normal. They have  
17    brain calcifications. And at the age of around six  
18    months, they begin to show signs of Zika. The brain  
19    begins to shrink and the head begins to shrink. So,  
20    you can have what you think is a "normal" child, but  
21    in time you find out that the child is in fact  
22    suffering from defects from Zika.

23            Yes, there is a correlation or there has  
24    been speculation of a correlation between people who  
25    have been infected with other diseases like dengue and

1     such, a correlation between that and Zika. So, in  
2     Brazil, there is a huge number of women who are  
3     pregnant and had a number of babies born with Zika.  
4     It turned out that they also had antibodies for like  
5     dengue and yellow fever and such. So, they believe  
6     that there may be some synergistic effect going on in  
7     the immune system. I'm sure there will be more  
8     research being done on that.

9             So, CDC leads this federal response effort.  
10    I'll say that again, CDC leads this effort. EPA and  
11    several other agencies, we help CDC and we meet  
12    regularly to discuss Zika and address Zika. We  
13    support CDC with information on integrated pest  
14    management and pesticide registration and use  
15    information.

16            Combined efforts show that in states where  
17    local transmission of Zika has been reported, such as  
18    Texas and Florida, mosquito control and public  
19    education efforts have succeeded in minimizing the  
20    impact of disease on human mosquito populations.

21            So, what that's getting at, as you'll recall  
22    this past summer, they were able to contain those  
23    additional infections by aggressive action with IPM as  
24    well as spraying of pesticides. So, while I think  
25    those areas still have what CDC considers yellow boxes

1 around them, the number of cases have not increased,  
2 for the most part.

3 Widespread public education campaigns  
4 address both residents and travelers to the area,  
5 encourage people in particular, pregnant women, to  
6 protect themselves from mosquito and Zika. Such  
7 measures include insect repellants on a regular basis,  
8 using window screens and other containment measures to  
9 keep these mosquitoes from coming indoors, which they  
10 love to do, discard standing water. Tire shredding,  
11 it's a huge issue in Puerto Rico, huge, tire shredding  
12 and removal, as well as avoiding areas where Zika  
13 transmission can take place. So, there are travel  
14 related warnings as well.

15 This next slide I sort of love because while  
16 the federal responses work to achieve comprehensive  
17 and sustained efforts on mosquito control, in light of  
18 Zika and other mosquito-borne diseases, and other  
19 diseases in general, the challenge remains. So, the  
20 black areas indicate those mosquito control  
21 districts that are active in those states that have  
22 not given up on mosquito control. So, they have  
23 active mosquito control activities going on. The  
24 white mass are those states that do not. So, this is  
25 a very poignant slide, I think.

1           So, not all parts of the country have a  
2 robust mosquito control program and/or adequate resources.

3       So, some of the states used to have very active  
4 mosquito control districts. As their budgets got  
5 smaller and smaller, they decided to cut back on  
6 things like mosquito control in public health. So, as  
7 a consequence, they're not quite ready.

8           So, it's sort of patchwork here in the  
9 United States. There are more than 700 mosquito  
10 control districts in the contiguous U.S., but there are  
11 a large number of states where no local level mosquito  
12 control districts exist.

13          CDC and EPA are reaching out to states that  
14 provide help to do this. We need to control both  
15 larvae and adult mosquitoes, control surveillance of  
16 mosquito populations, their resistance, and increase  
17 personal protection largely through community wide  
18 approaches. We also need to establish vector control  
19 units in Puerto Rico. Of course, we're always looking  
20 for new tools and techniques that we can use.

21          Many of the efforts that are needed to  
22 reduce mosquito populations rely upon actions of  
23 property owners and residents to remove breeding  
24 sites. Folks, this is where the federal and state  
25 authorities have little control. So, we're talking

1     about your backyard. So, if you've got standing  
2     water, tip and toss. Teach your children how to do  
3     it. Those are breeding grounds for mosquitoes.

4             There's a bright side, and there's a bright  
5     future ahead, I believe. I'm going to be the optimist  
6     here. While EPA -- this not our area of work. I  
7     thought it would be important to put up a slide here  
8     on vaccine development. I'd like to report that  
9     vaccine development is underway and is looking  
10    promising. According to recent articles, it looks  
11    like there is promising news on the vaccine front.  
12    You can look up those articles and take a read when  
13    you get a chance.

14            Just so you know, phase one trials of  
15    vaccine development are ongoing, and they're looking  
16    toward phase two. During phase one, small groups of  
17    people received the trial vaccine. In phase two, the  
18    clinical studies expanded, and the vaccine is given to  
19    people who have characteristics similar to those for  
20    whom the new vaccine is intended. In phase three, the  
21    vaccine is given to thousands of people and tested for  
22    safety and efficacy.

23            At this point, the vaccine can be licensed.  
24    Even though there's still a phase four, which roles  
25    out ongoing studies of the vaccine. Use of live

1 attenuated vaccine is the best kind to give the best  
2 response. So far, the vaccine match seems to be very  
3 good for live attenuated vaccine. So, that's some  
4 good news.

5 The antibody response is reported stronger  
6 than response to the actual virus. So, good news  
7 there. All this means that we may have a viable  
8 vaccine. I don't want to throw out a time frame, but  
9 we're probably looking at a year to two years. I  
10 really can't put a time frame on it. Certainly, this  
11 is not EPA's area of expertise. This is certainly  
12 information from CDC.

13 In the meantime, especially starting this  
14 year and continuing, a strong partnership of federal,  
15 state, and local level officials have improved methods  
16 and approaches for controlling the mosquitoes and  
17 primary carriers of Zika. CDC and the states have  
18 strongly coordinated surveillance systems to monitor  
19 public health. CDC also worked hard during the  
20 winter, and I have to give them a whole lot of credit,  
21 to increase awareness and communications, closely  
22 collaborating with state agencies and mosquito  
23 control boards.

24 I mentioned that we meet with CDC on a  
25 regular basis, and this is one of the suggestions that



1 EPA provided CDC, that we use this winter as a time to  
2 prepare and train and develop and come up with  
3 community strategies. CDC has done just that. They  
4 have just been all over the place communicating,  
5 giving seminars and webinars and talking to states, et  
6 cetera, and communities. So, hats off to CDC.

7 Some mosquito control districts have ramped  
8 up as a result not only their own hiring, training,  
9 and preparedness, but also the information that they  
10 develop and disseminated in the communities. This is  
11 a community effort if we're going to be successful.

12 Because it is a public health emergency, EPA  
13 is also expediting registrations. You all are aware  
14 of that. We have expedited registrations, including  
15 emergency exemptions or Section 18s, and registration  
16 amendments for pesticides and repellants that have or  
17 want Zika claims.

18 At this point, I'm going to turn it over to  
19 my colleague, Yu-Ting, who is going to walk you  
20 through some of the eco and health risk assessments  
21 for mosquito control pesticides.

22 MS. GUILARAN: Thanks, Arnold. So, I have a  
23 couple slides to go through just to update folks on  
24 the pesticide tools that are available and are going  
25 through the registration review process right now.

1           As you can see, a lot of them, they are  
2   insect growth regulators with a couple that are  
3   on this slide. A few of the organophosphates are also  
4   on this slide. Then, the next kind of class of  
5   chemicals that we have here is pyrethroids.

6           They're in the various stages of the reg  
7   review process right now. For a good handful of them,  
8   the risk assessment is planned for this year. For a  
9   few of these, the risk assessment has been completed  
10   and has been published. We have gotten the comments  
11   from the public comment process. So, that spinosad  
12   and also malathion. And then we have ones that are  
13   planned this year in 2017. We have naled and DDVP.  
14   And then chlorpyrifos, obviously, the human health  
15   risk assessment was out back in November.

16           For the pyrethroids, we have the ones -- all  
17   the ecological risk assessments have been completed.  
18   The human health, a handful of them, did go out with  
19   the first batch. So, we're in the process of  
20   completing human health risk assessments. So, that  
21   includes the last chemical that's on the slide and all  
22   of the following slide, 15, here.

23           So, as you can see, some of these we have  
24   the assessment completed, and we will be soon  
25   extending the comment period once the Federal Register

1 notice is out, like what I said this morning, and then  
2 that will get another 60 days for people to submit  
3 comments to us.

4 So, our overall plan for the pyrethroids is  
5 that we'll come out with our proposed interim decision  
6 in 2018, following getting the comments from the  
7 public and assessing them and see if there's any  
8 change that we need to make. So, that's overall the  
9 schedule.

10 So, moving on to slide 16, just to reiterate  
11 that, the public input is really important to the reg  
12 review process. These are the chemicals that have  
13 been used for a long time. We know that a lot of  
14 times the label and use patterns drive the risk. So,  
15 it's really important for us to get feedback on detail  
16 use and usage information, especially data that will  
17 be the most helpful.

18 Then, geographic location of use can  
19 sometimes help us refine the risk. And then, also,  
20 after we have had a chance to look at all the risk  
21 assessments in terms of developing risk mitigation  
22 strategy, that's another area that we will solicit  
23 input and also work with the registrants and different  
24 stakeholders, USDA, then grower groups, or other CDC,  
25 for example, to figure out different ways to mitigate

1 a risk. Then, lastly, as an overall, the risk benefit  
2 balancing that I talked about this morning as well.

3 MR. LAYNE: Thank you, Yu-Ting. So, moving  
4 on to the next slide, I'm not going to spend a lot of  
5 time on it because you are well aware and  
6 knowledgeable about some of the things that we're  
7 doing that go beyond conventional pesticides.

8 We're also reviewing the new methods for  
9 controlling mosquitoes, currently assessing for safety  
10 and efficacy. That includes Wolbachia and Oxitec.  
11 So, I'm not going to spend a lot of time. I think Bob  
12 McNally and his group have done a fantastic job  
13 talking about that, so I won't spend a whole lot of  
14 time here.

15 I talked to some children, just to put a  
16 little smile on your face because it made smile. We  
17 had a bring your son or daughter to work day. I had  
18 to give an opening because my boss here didn't have  
19 time to do it. I was trying to be nice. So, I had a  
20 blast teaching them about many things, but of course I  
21 had to bring up Zika and mosquitoes.

22 So, one of the coolest things that they  
23 really appreciated and learned -- or actually two  
24 things. One is they will keep on their parents about  
25 tipping and tossing. Number two, they were amazed to

1 find out that just girl mosquitoes bite. So, I had a  
2 good time with them.

3 Anyway, the next slide on IPM. Bob, jump in  
4 at any time. You've done quite a bit of work in this  
5 arena. So, obviously, vector-borne diseases pose  
6 significant public health problems. We all know that.  
7 There's wide recognition that implementing IPM  
8 techniques is so critically important to successfully  
9 controlling disease vectors.

10 I want to stress that EPA strongly supports  
11 and is a huge proponent, and advocate for IPM, as we  
12 work with CDC and state agencies to monitor mosquito  
13 populations and target control measures, inform and  
14 engage the public and ultimately reduce vectors.

15 EPA plays a critical role in evaluating and  
16 streamlining registration process for many new novel  
17 and emerging pesticide technologies. We also provide  
18 guidance and expertise in safe and effective use of  
19 EPA registered pesticides as part of an overall vector  
20 management program. Obviously, when you're in  
21 situations like this, sometimes there could be quite a  
22 lot of misuse. So, we do our best to make sure that  
23 doesn't happen through education.

24 This next slide I'm going to hand it over to  
25 Bob. It's some of the stuff that he and his folks

1 have been doing in Texas with the IPM Center of  
2 Expertise.

3 MR. MCNALLY: Thanks, Arnold. So, as a lot  
4 of you know, we've talked before, we have an IPM  
5 Center of Expertise in Dallas. As Arnold alluded to,  
6 a lot of the benefits of IPM accrue as part of an IVM  
7 program. What we've done is supplemented the work of  
8 that group to include some IVM work.

9 We've added Ken McPherson, who  
10 was the region's sixth IPM coordinator, on a detail to  
11 the center starting this month. Ken's background is  
12 he was at the Defense Department before he joined EPA.  
13 He was sort of their expert on IVM and led efforts in  
14 the Pacific theater. So, we feel we have not only a  
15 national expert but an international expert to help  
16 us. I think where we help the cause of CDC is we  
17 bring the knowledge of pesticides to the table.

18 How do you combine that with IPM and an IVM  
19 program? To help some of those local communities that  
20 Arnold highlighted on the chart a little bit earlier  
21 that had the white space, that don't have an active  
22 mosquito control program, we think we can help with  
23 our expertise in those areas and others to help people  
24 deal with these issues as they come up, hopefully not  
25 this summer. But if they do, we want to stand ready

1 to be helpful.

2 MR. LAYNE: So, IPM partnership  
3 opportunities, CDC again is the lead federal agency  
4 for responding to public health emergencies, including  
5 vector-borne diseases. This also means that they are  
6 also the lead for recommending mitigation techniques  
7 to state and local agencies to address both disease  
8 and pest mitigation.

9 Recently, CDC awarded nearly \$40 million to  
10 4 universities to establish centers that can help  
11 effectively address emerging and exotic vector-borne  
12 diseases in the United States. Since there are  
13 significant regional differences in vector ecology,  
14 disease transmission dynamics and resources across the  
15 country, the centers are geographically disbursed and  
16 include the University of Florida, the University of  
17 Texas Medical Branch at Galveston, the University of  
18 Wisconsin in Madison, and Cornell University.

19 So, CDC has done quite a bit again. I can't  
20 thank them enough, and also their willingness to come  
21 together as a federal body. Several agencies came  
22 together, including the White House and others on this  
23 very important issue.

24 Next slide, please. So, that leads to --  
25 and I can't tell you how much I appreciated in the

1 last PPDC, which is my first one in probably 15 years  
2 that I had been to, but just the overwhelming support from  
3 folks saying that they really would like to help in  
4 any way they can, help the Agency and help in this  
5 effort.

6 So, they wanted to bring back or  
7 reconstitute the public health workgroup. We took  
8 that back and we thought about it. We decided that we  
9 would like to move forward with that. So, with that  
10 in mind, we agreed.

11 There are some caveats, however, so that we  
12 do not get in trouble. One is there needs to be a  
13 defined time line. So, you're looking at a one to two  
14 year group. We really need to decide an area that  
15 we're going to focus on, or areas that we're going to  
16 focus on. So, sort of a finite set of areas that we  
17 would be charged with. It could just be one or it  
18 could be many.

19 I thought I would throw out just one up  
20 there. We are hoping to hearing from you, obviously,  
21 but I thought I'd get the conversation started. So,  
22 what we're proposing is -- and by the way, this is not  
23 just open to PPDC. We need at least one full-time  
24 member of the PPDC on this workgroup, and I imagine  
25 that I will not have a problem getting at least one



1 person, right, Dawn?

2 MS. GOUGE: I actually rotate out.

3 MR. LAYNE: Oh, you do? Oh, no.

4 MS. GOUGE: I'm afraid so.

5 MR. LAYNE: Well, you can still be on a  
6 workgroup. So, anyway, I'm sure there is at least one  
7 person staying on the PPDC who would be interested in  
8 helping us.

9 In any event, I thought that perhaps a  
10 discussion on Zika and other emerging pathogens,  
11 because they seem to be coming constantly, would be  
12 someplace to start. But there are a plethora of other  
13 topics that fall under this category of public health.  
14 So, we'd like to hear from you some of those  
15 suggestions and whether you're interested in serving  
16 on a group.

17 I will tell you that I would like to keep  
18 the group to no more than 20. Otherwise, it gets  
19 unwieldy. If you can send me or Dea, or actually send  
20 to Dea, your suggestions, A, if you want to  
21 participate and B, some areas for consideration that  
22 we can talk about and work on. That would be  
23 fantastic.

24 The next slide is just some discussion  
25 questions. I don't know if we still have time to do

1       that. I have 12 minutes left, and that was just from  
2       my presentation.

3               MR. KEIGWIN: Are you asking for a  
4       well done or something?

5               MR. LAYNE: Yes, and some water. Jackie  
6       professed to be from New York. I'm from New York as  
7       well. I think I went faster than her.

8               Anyway, we've got a couple questions for you  
9       to consider. Do you agree that the formation of a  
10      public health workgroup is ripe? I see some thumbs  
11      up. Yes? So, we want to move forward with that.

12              Again, please provide feedback and ideas on  
13      the charge that I proposed that perhaps we focus on  
14      Zika. But I'm open to whatever you think is most  
15      important and something that is well defined and that  
16      we will be able to complete within a reasonable amount  
17      of time. Send that information to Dea by May 17th.

18              What would be the benefits that EPA, and not  
19      just EPA, but everyone, could gain from this  
20      workgroup, focusing on Zika, if we were to go down  
21      this path? It's something to think about.

22              What other areas of public health and  
23      emerging pathogens would you advise would be  
24      appropriate for the workgroup to undertake?

25              Again, do you have any additional

1 suggestions for us to consider?

2 So, some discussion questions. With that, I  
3 open it up to you all.

4 MR. KEIGWIN: So, why don't we start with  
5 Fred, then Robyn, then Amy.

6 MR. STELL: Thank you. I just want to add  
7 that I think this formation of a public health  
8 workgroup would be -- DOD would be very interested in  
9 sending a representative from the Armed Forces Pest  
10 Management Board. We deal with not only items for the  
11 public health toolbox to be used on our installations,  
12 but also our overseas contingency operations, as well  
13 as some of the unique challenges that DOD faces with  
14 aircraft disinsection. That may also affect  
15 Department of Transportation.

16 We've seen with disinsection being  
17 implemented for public health purposes for entry into  
18 other countries, it's very important to stay engaged  
19 with those topics. We'd definitely like to be  
20 involved.

21 MR. LAYNE: Wonderful. So, we've got at  
22 least one PPDC member, so we can form a workgroup.

23 MR. STELL: This is supposed to be my last  
24 meeting, but my replacement definitely would like to  
25 be involved.

1 MR. LAYNE: Is there anyone here who --

2 MR. KEIGWIN: Everyone is going  
3 through membership.

4 MR. LAYNE: Everyone is going. Oh, geez.

5 MR. KEIGWIN: Some folks are term limited  
6 and couldn't apply for renewal.

7 Robyn, then Amy, then Marc.

8 MS. GILDEN: So, I've got to get myself  
9 together here because I have a couple of disparate  
10 comments to make. Yes, I think a public health  
11 workgroup is awesome. As for who can represent from  
12 the PPDC, you're losing three of the four existing  
13 public health representatives. So, Amy, it looks like  
14 it's going to be you. I mean, I'm hoping that you're  
15 going to replace the public health representatives.  
16 I'm willing to help, but I'm term limited off.

17 MR. LAYNE: Thank you.

18 MS. GILDEN: As for the IPM workgroup, I was  
19 privileged enough to serve on that for the six years  
20 that I've been on it. I'm very disheartened and  
21 disappointed to see that is not going to continue  
22 as the school IPM. I'm getting ready to give a talk  
23 to the School Nurses Association on Tuesday. I don't  
24 really see any follow up from the roundtable, which  
25 they were an important part of. So, I will continue

1       that conversation on behalf of the EPA.

2               I'm going to take the prerogative to talk  
3       about something that we weren't supposed to talk about  
4       because it's my last meeting. Just to say that on  
5       chlorpyrifos, the update that we were given, you  
6       denied a petition from March 29th requesting  
7       revocation of the tolerances that was submitted by the  
8       Pesticide Action Network and NRDC. Then you say that  
9       the neurodevelopmental effects are still unresolved  
10      and we're looking into it. So, you're not going to do  
11      anything further until October of 2022.

12             This is mind boggling. You say the  
13      neurodevelopmental effects remain unanswered, but yet  
14      you won't do anything to take it out of the food until  
15      it's answered. But then, you're still allowing it to  
16      be in the food. So, that's just my comment.

17             MR. KEIGWIN: Bob, did you want to address  
18      anything about follow up to the school IPM?

19             MR. MCNALLY: Yes, thanks, Rick. So, we are  
20      following up, Robyn, with the group. I think you guys  
21      were aware of the work that we did about this time  
22      last year. That work continues. We're trying to get  
23      a sense of what activities they are pursuing on their  
24      own and how we can help them in that follow through.

25             Our commitment last year was over a three-

1 year period to continue in that vain. I think the one  
2 thing within EPA is that I think, Rick, this year it's  
3 no longer on the list of regional priorities. So, the  
4 regions will not have that as something they can  
5 pursue. But our intention is to continue our efforts  
6 through the Center of Expertise in Dallas in the areas  
7 that we have control over here at headquarters.

8 MS. GILDEN: I know you've been working with  
9 NEHA, but I don't know how aggressive  
10 you've been working with the other participants that  
11 participated in the roundtable. The only nursing  
12 organization I'm aware of is the school nurses. I've  
13 not seen anything that they've been doing. I was  
14 invited to talk at this conference on Tuesday, and  
15 they asked me, we don't have anything on environmental  
16 health. Can you come present on environmental health?  
17 I was like okay, sure.

18 MR. MCNALLY: Thanks. We've be happy to  
19 meet with you and share some of the things that we're  
20 doing and some of the members of the roundtable who  
21 are following up on their own. I don't recall offhand  
22 all the different groups, but we're happy to talk to  
23 you about what they're doing.

24 MR. KEIGWIN: Amy, then Marc, then Dawn.

25 MS. LIEBMAN: Thanks, Robyn, for those

1        comments. Thanks for that presentation on Zika.

2        That's a really important issue.

3                I resubmitted my application or nomination.

4        So, if I'm around, I would be happy to serve on this.

5        I do suggest, and this is a suggestion from the past,

6        I think we should be careful with the term public

7        health. I think it should be the public health and

8        emerging pathogens group because it's a pretty broad

9        topic and there's lots of public health issues

10       relating to pesticides. So, I think that would help

11       clarify that somewhat.

12               Then the other comment I wanted to make is

13       in terms of the work that you're doing with CDC. I

14       think that's great that you're such a strong partner

15       with CDC. But one thing, EPA, believe it or not, is

16       actually ahead of CDC in terms of clinician education

17       regarding the recognition and management of pesticide

18       poisonings.

19               I think that there's a lot of --

20       particularly when we're looking at the types of

21       pathogens that you mentioned and Zika and the type of

22       pesticides that are used to control mosquitoes and are

23       being used to control mosquitoes and used to control

24       Zika, that there's got to be a really important part

25       of the outreach that you do to make sure that

1 clinicians are very much aware of the health effects  
2 of the pesticides that are being used. There's  
3 several organophosphates that are involved.

4 There's a community piece and the outreach  
5 piece, but in terms of advising CDC, because they tend  
6 to ignore this part of it, is that take note from what  
7 EPA has done in terms of trying to help educate  
8 clinicians. That should be a key piece of the  
9 outreach that they're doing in terms of the role  
10 that's used for Zika and other emergent pathogens.

11 MR. LAYNE: Thank you, Amy, for that. I  
12 will pass that along.

13 MR. KEIGWIN: Okay, Marc, then Dawn, then  
14 Gabrielle.

15 MR. LAME: So, I'm rotating off. This is an  
16 interesting workgroup. I'm pretty sure that Bob told  
17 me that the reasons they got rid of all the other  
18 workgroups and had this term period is to make sure  
19 that I'm not around to bother you people anymore. At  
20 any rate, I might say that as a parting member that  
21 this type of public service is very rewarding, and I  
22 appreciate the opportunity.

23 As far as this type of program, I think it's  
24 a smart move. When I heard, and I did hear that they  
25 were moving from school integrated pest management,



1 the center of the universe, to this, I actually  
2 thought it was a good idea.

3 My recommendation is to utilize the  
4 infrastructure that you already have in place. You  
5 have a vast infrastructure of a number of different  
6 governmental agencies, but also of change agents for  
7 integrated pest management that are well versed in  
8 this.

9 In fact, in my opinion, probably the best  
10 mosquito district, the most advanced mosquito district  
11 in the country, is New Orleans with Claudia Riegel.  
12 She was part of a team that Dawn and I  
13 were on that did education to public health folks  
14 throughout the country. Claudia is just the best.  
15 Her facility is the best that I know of. So, I'll  
16 volunteer her.

17 MR. LAYNE: Please do. And I assume that  
18 you're volunteering yourself as well, right?

19 MR. LAME: If asked, I will serve, but  
20 you've got to deal with your own folks.

21 MR. LAYNE: I have to hear from you that  
22 you're interested by May 17th, right?

23 MR. LAME: Yes, you'll hear.

24 MR. LAYNE: All right, thank you.

25 MR. LAME: So, what has happened both with

1 CDC and EPA with regard to integrated pest management  
2 in different ways is the digitalization of a wholesale  
3 approach to get information out. Where I see the  
4 value of that, to some extent, I think in this type of  
5 situation, you really have to do both. You have to go  
6 back to a retail approach going into specific areas  
7 with your experts and integrated team, as it were, and  
8 deal with situations. It will literally be saving  
9 lives at that point, rather than a theoretical thing  
10 about let's get out more information and count beans.  
11 So, I think that that's really important. This is  
12 something that Fred understands well when we get into  
13 that kind of stuff.

14 Then, finally, I would say that a strategic  
15 plan for the Center on Expertise is something that is  
16 definitely needed, would be probably in consultation  
17 with your administration, would be one of the most  
18 important first steps that you can take towards this.  
19 So, thank you.

20 MR. KEIGWIN: Dawn, then Gabrielle, then Lori  
21 Ann.

22 MS. GOUGE: Thank you. I am thrilled that  
23 you're forming a public health workgroup. Thank you  
24 so much for that. I'm disappointed that I'm not going  
25 to be here in person, but I will serve. Happy to

1     serve.

2             I did want to point out, as we recognize  
3     that school IPM, the Center will not focus on school  
4     IPM, I'm also very thrilled that they're going to  
5     focus on vector. I think Ken will be an awesome  
6     addition to that team.

7             But I did want to let everybody know that  
8     there is still a national school IPM steering  
9     committee and full workgroup, regional workgroups  
10    around the country, focusing on school IPM. So, we'll  
11    stay connected on what's happening.

12            I wanted to add a few sobering statistics to  
13    what Arnold shed in his report. That is if you add  
14    the microcephaly cases at birth with the post-partum  
15    cases that develop over time, it's close to 1 in 10  
16    babies are impacted. If you look closer at those moms  
17    that had Zika in their first trimester, it's closer to  
18    1 in 7. So, this is a really significant issue.

19            I would also like to encourage the new  
20    public health workgroup that yes, a focus on Zika for  
21    sure, at least initially. But we do have significant  
22    issues with ticks as vectors and also bed bugs, not as  
23    vectors. But I would really encourage even maybe if  
24    it's possible to form subgroups within your team at  
25    some point. And then, with regard to additional

1 suggestions, vector resistance issues, for sure.

2 Thank you very much. And thank you so very  
3 much for the experience and the ability to serve.  
4 I've really enjoyed it.

5 MR. KEIGWIN: Gabrielle, then Lori Ann, then  
6 Jim.

7 MS. LUDWIG: So, a couple things. I mean,  
8 public health is not necessarily my forte. Actually,  
9 Dawn, you mentioned some of the things I was going to  
10 mention. Certainly, as a hiker around this area,  
11 ticks and the diseases they transmit is becoming much  
12 more of an issue. I do think that whoever said we  
13 need to define this carefully --

14 Really, what we're talking about is mosquito  
15 control. It's not just Zika. You've got a whole  
16 bunch of other diseases that are mosquito related.  
17 Zika is just the one that's giving us the heebie jeebies,  
18 rightfully so, and so I think that definition of being  
19 clear on how we're defining it.

20 The flip side of it is, and I think since  
21 we're the PPDC, is you have this tension of the  
22 benefits of the pesticides and the risks of the  
23 pesticides. So, somewhere there has to be some more  
24 conversation about that. The risks are not only the  
25 human health risks or the environmental risks, but

1       there's even an ag risk that I think we have one  
2       almond load that supposedly got rejected because it  
3       had pyrethroid residue. We didn't have an MRL in the  
4       EU. That's being blamed on a mosquito spray. I don't  
5       know if that's totally factually true, but I'm just  
6       saying there's little things like that that can come  
7       up as well.

8               So, I think what I would like to see is help  
9       you get the advice of what are the things that you as  
10      the Agency need to think about as you're trying to  
11      find additional tools to help minimize the mosquito or  
12      tick or I've recently had to deal personally with bed  
13      bugs. So, I am quite versed now in how to deal with  
14      them, because I did not get professional help when I  
15      wanted it, so I had to figure it out on my own.

16             And then the full resistance management and  
17      dealing with the public on it is -- I haven't really  
18      heard a clear statement of how do we look at the risks  
19      and the benefits and manage that and the  
20      communications of it, given that we have a real public  
21      health risk from the mosquitoes and the ticks.

22             MR. KEIGWIN: Lori Ann, then Jim, then  
23      Nichelle.

24             MS. BURD: First a question and then a  
25      comment. Do we have any information about Zika? My

1 understanding is that a Zika mosquito needs to bite an  
2 infected person, and that's the way the mosquito gets  
3 infected with Zika. And it's not transmitted mosquito  
4 to mosquito. Is that correct? So, my question is  
5 whether the host could also be an animal. Just  
6 curious whether it could be a dog, cat, wild animal,  
7 primate.

8 MR. LAYNE: The hosts in the U.S. at  
9 least are humans. There are some primates that kind  
10 of also serve as a reservoir, but humans would be the  
11 only reservoir here.

12 MS. BURD: Thanks. My comment is because we  
13 know Zika is sexually transmitted, I would encourage  
14 the use of condoms and condom distribution as an IPM  
15 method, especially for women who are pregnant or may  
16 be pregnant who may be taking all the good measures  
17 we've been talking about, but may have a husband who  
18 is not being quite as cautious, to ensure that we're  
19 looking at all the modes of transmission and not just  
20 the mosquito-borne modes.

21 MR. LAYNE: We dealt with that issue with  
22 some of the U.S. territories. It is a very difficult  
23 issue because there's religion that comes into play.  
24 There's just a plethora of issues that come into play.  
25 I think there's talk about that.

1           I'll use Puerto Rico as an example. It  
2     turned out to cause some concern that kits were being  
3     passed out that contained contraceptives. Also, it  
4     gives a connotation that the husband may be doing  
5     something that he should not be doing outside of his  
6     vows. But, quite frankly, he could have gotten bit.  
7     Apparently, the virus hides in the male testicles.  
8     They don't know for how long.

9           So, you can encourage. I think that's all  
10    the concern that you've heard about telling women who  
11    are thinking of getting pregnant to avoid areas of  
12    Zika transmission, of local transmission in  
13    particular, and also in men. It's rare, very rare  
14    that I hear about the male part of this dynamic.

15           It's a real issue because the woman can do  
16    all she can if she wants to get pregnant and not  
17    realize that her partner actually had been infected  
18    until she gets that sonogram. So, that's a very  
19    touchy issue from a religious standpoint in some parts  
20    of the United States. But thank you for that.

21           MR. KEIGWIN: Okay, Jim and then Nichelle.

22           MR. FREDERICKS: So, not to diminish the  
23    importance of Lori's comments, I think it definitely  
24    has merit. But I like the idea of birth control being  
25    described as pest control. So, maybe if someone would

1     have explained it to me that way, I would have got the  
2     hint.

3             Then, also, if anyone finds themselves in a  
4     situation where, as Gabrielle did with bed bugs, we'd  
5     certainly be able to point you in the right direction  
6     of a professional having to do that.

7             So, from NPMA's point of view, definitely  
8     thanks to Arnold and your team for all the hard work  
9     that you've been doing with regard to Zika. For sure,  
10    I know that it's taken more time probably than you  
11    ever imagined, but it's important work, and we commend  
12    the Agency for it.

13            I wanted to also then just reaffirm the  
14    structural pest management industry's commitment to  
15    integrated mosquito management, IPM. We found  
16    ourselves in a unique position because oftentimes we  
17    don't think about mosquito control as being a  
18    structural pest management issue. But with these  
19    mosquitoes, with Aedes mosquitoes, oftentimes what you  
20    have is a mosquito that is uniquely adapted for living  
21    with humans and living around humans.

22            The structural pest management history has  
23    150,000 trained technicians that are visiting between  
24    8 and 12 houses a day. So, the boots on the ground  
25    in the backyards tipping and tossing. So, I'd be



1 happy to serve on the workgroup. I think I do want to  
2 echo the idea that right now Zika is important. It's  
3 up on the top of mind.

4 But we also shouldn't ignore some of the  
5 other public health threats with regard to ticks,  
6 obviously Lyme disease, as well as the other mosquito-  
7 borne illnesses, and the other public health threat  
8 that pests in general also present, such as  
9 transmission in food-borne illness, that sort of  
10 thing. So, thanks.

11 MR. LAYNE: Thank you. There's a new tick  
12 disease. There's one case in Connecticut that I just  
13 read about. I can't remember the name of it. So, it  
14 is definitely an issue, broad issue. So, ticks will  
15 be an issue this year as well. And this particular  
16 one hadn't been seen in quite some time. It's a lot  
17 more deadlier.

18 MR. KEIGWIN: Nichelle.

19 MS. HARRIOTT: I just have two very quick  
20 comments on this very important issue. With regard to  
21 the registration review of the pesticides that are  
22 registered for mosquito control, I am urging the  
23 Agency to take a very deliberate stance in conducting  
24 their assessment for mosquito exposures because it's  
25 very important that people have all the information

1 available regarding human health exposures to the use  
2 of the pesticides for mosquito control.

3 And then secondly, just echoing what has  
4 already been said around the room when it comes to  
5 public education. Again, it will be very helpful,  
6 especially for local officials who are tasked with  
7 making decisions for mosquito control, that they are  
8 aware of some of the human and environmental health  
9 risks when it comes to making these applications so  
10 they have all the information to make an informed  
11 decision.

12 MR. KEIGWIN: Are there any PPDC members on  
13 the phone that wanted to make a comment? We'll open  
14 up the lines.

15 (No verbal response.)

16 MR. KEIGWIN: All right. We have one person  
17 here in the room that signed up for public comment,  
18 and she promised me it would be no more than three  
19 minutes. So, Julie.

20 MS. SPAGNOLI: I just wanted to go back and touch  
21 on the GHS labeling issue. We looked at this many  
22 years ago. One of the issues is converting from the  
23 current pesticide labeling categories to GHS  
24 eliminates the caution category. There is no caution  
25 in GHS.

1           This would not be such a big issue just for  
2 registrants just to relabel their products and not  
3 have caution on their label, but there's a lot of  
4 implications. School IPM programs, municipal IPM  
5 programs, procurement programs, a lot of these  
6 programs utilize that caution signal word as a  
7 criteria. So, with the caution signal word going away  
8 completely, it could have implications. So, you would  
9 need a fairly robust public education effort to  
10 explain that.

11           In addition, also like extension programs  
12 that explain labeling to consumers, they'll often  
13 refer to caution, the caution category. So, one of  
14 the things to think about in considering GHS should  
15 that caution category go away, that could cause some  
16 significant downstream effects.

17           MR. KEIGWIN: Thanks, Julie.

18           Dawn, did you have a comment?

19           MS. GOUGE: Just a quick comment in response  
20 to that. So, there's already a great deal of  
21 confusion because the SDS signal words are harmonized  
22 or whereas the label signal words are quite often different.  
23 So, there's already a lot of confusion. So, I'm keen to  
24 just have it all the same. Yes, you're absolutely  
25 correct, some education would definitely be warranted.

1 MR. KEIGWIN: Thanks, Julie.

2 If there's anyone on the phone that wanted  
3 to make a public comment, we'll open up the line.  
4 Anyone participating over the phone that wanted to  
5 make a public comment?

6 (No verbal response.)

7 MR. KEIGWIN: Okay.

8 MR. HANSON: I'm Jaydee Hanson with the  
9 International Center for Technology Assessment. We  
10 have commented on the FDA's docket with respect to  
11 genetically modified mosquitoes. In those comments,  
12 we've actually recommended that the EPA, because of  
13 your better experience in evaluating insects, should  
14 actually be in charge of all of the genetically  
15 engineered, sterile insects, whether they're at FDA or  
16 whether they're at USDA. We believe that the EPA  
17 should be the first stop on that.

18 With respect to your new task force that  
19 you're talking about, part of my background is in  
20 bioethics. I think you're in some ways with the way  
21 you're dealing with Zika walking out on some dangerous  
22 grounds in ethics.

23 There are many things that cause  
24 microcephaly. (b)(6)

25 (b)(6) Fortunately, it's one of the more

1       treatable. But alcoholism causes microcephaly.  
2       Toxoplasmosis causes it. There are many things.  
3       Part of the job that we need to be doing is making  
4       sure the public gets good information. A few years  
5       ago Alaska had the most cases of microcephaly. It's a  
6       serious illness. It's a serious birth defect. There  
7       are (inaudible) that cause it as well.

8               So, as the EPA and the CDC do their work,  
9       this is awful. No child should be born this way. But  
10      there are many other conditions, including a number of  
11      chemicals, that cause microcephaly. So, please be  
12      careful how you deal with that.

13             I would urge that your task force actually  
14      look at all of the arboviruses. There have been over  
15      2,000 people die from West Nile disease in the United  
16      States since that epidemic began, one of my neighbors  
17      here in northern Virginia. So, I would urge you to  
18      look at all the arboviruses and educate about  
19      microcephaly in a more complete manner. Thank you.

20             MR. KEIGWIN: Okay, thank you. That  
21      concludes today. Thank you all for sticking through  
22      the entire time. Tomorrow we're starting at 8:30. I  
23      think I mentioned earlier we have a couple hundred  
24      people who have registered to attend in person, so  
25      that will make -- oh, sorry, 100 total. I overspoke.

1       Nevertheless, that still means getting through  
2       security will likely take you a little bit longer.  
3       So, please try to plan accordingly.

4               The other thing I think I should mention for  
5       PPDC members, because of the additional people, we  
6       will not have coffee here. So, bring some. You may  
7       need it. But factor that into your time getting to  
8       the building.

9               I think that's it. Thanks for the great  
10       discussions today and the input. We really do  
11       appreciate it. Have a good night.

12                       (Whereupon, the meeting was  
13                       adjourned.)

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UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

DAY TWO - MAY 4, 2017

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202



## P R O C E E D I N G S

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MR. KEIGWIN: Welcome, everyone, to the second day of the Pesticide Program Dialogue Committee Meeting. For those of you who weren't here yesterday, I am Rick Keigwin. I'm currently the Acting Director of the Office of Pesticide Programs.

We're going to be spending the morning today getting public input on potential regulatory reform efforts in response to President Trump's Executive Order 13777. I want to thank in advance all of you who have come to participate in this meeting in person and to those of you that are joining us over the telephone.

Just a little bit of background on this new executive order. President Trump issued the order entitled "Enforcing the Regulatory Reform Agenda" on February 24th of this year. In that order, it directs each agency to develop a regulatory reform task force to oversee the evaluation of existing regulations and to make recommendations about potential repeal, replacement, or modification of those regulations. The executive order also requires the task force to seek input from a variety of entities significantly affected by EPA regulations. So, that's one of the

1 purposes of today's meeting.

2 In March of this year, EPA Administrator  
3 Pruitt issued an Agency-wide memorandum on  
4 how we would be implementing this executive order at  
5 EPA. And among other things, it announced the members  
6 of the Regulatory Reform Task Force, which is headed  
7 by Samantha Dravis in our Office of Policy.  
8 It also describes how the task force is charged with  
9 evaluating existing regulations and making  
10 recommendations to Administrator Pruitt.

11 The Office of Chemical Safety and Pollution  
12 Prevention intends to submit a draft report of our  
13 findings to the task force by May 15th in response to  
14 Administrator Pruitt's memo.

15 So, I know for those of you on the PPDC,  
16 you're seated in a slightly different way than you  
17 normally would, this is to accommodate a high turnout  
18 of people that registered to participate. I think we  
19 have almost 100 people who registered to participate  
20 in person and a very large number who are joining us  
21 over the telephone. So, thank you for your patience  
22 and your flexibility for today.

23 For us at EPA, this is a listening session  
24 to hear your thoughts on which pesticide regulations  
25 should be repealed, replaced, or modified. We will

1 not be reacting to any of the comments that are made,  
2 but we are here to listen.

3 There will be a transcript generated from  
4 today's meeting, and we will post a copy of that  
5 transcript in the docket for the PPDC, as well as on  
6 the PPDC web site. That will probably take us a  
7 couple of weeks, but it will be there.

8 While we will be taking notes today, we  
9 strongly encourage anyone making public comments to  
10 also submit those to the docket that was created for  
11 this effort. The docket for this effort currently  
12 closes on May 15th. There is an information sheet.  
13 If you haven't received it, that gives a little bit  
14 more guidance on how to submit those comments and what  
15 the docket number is at regulations.gov.

16 So, a couple of logistics for today. We'll  
17 first be taking comments from members of the Pesticide  
18 Program Dialogue Committee who are seated up front  
19 with us. We have about 20 members of the PPDC who  
20 told us in advance that they intended to provide  
21 comments. If we still have time remaining before the  
22 break, we'll open it up to the full PPDC to see if  
23 there are any other comments that they'd like to make.

24 And then, after the break, we'll hear from  
25 people from the public who have signed up to provide

1        comments in person. For those of you in the room,  
2        we'll ask you to step up to the microphone. For those  
3        of you on the phone, we will work through the  
4        logistics, and Claire Gesalman from the  
5        Office of Pesticide Programs will help moderate that  
6        part of the proceedings.

7                Anyone who is going to provide public  
8        comment today, we ask that you, when it's your turn to  
9        speak, to begin by saying your name and your  
10       organization that you are representing. Because of  
11       the high number of people that have requested to  
12       speak, we are limiting people to three minutes so that  
13       we can accommodate all of the numbers.

14                Dea Zimmerman, who's standing up to my left,  
15       your right for most of you, will give you a one minute  
16       warning sign. So, we're not going to cut off your mic  
17       or anything, but in the interest of letting as many  
18       people speak as possible, try to limit your comments  
19       to three minutes.

20                And then, one last thing, for those of you  
21       on the phone who don't have the advantage of the one-  
22       pager that we handed out, if you're interested in  
23       receiving a copy of that one-pager, you can send an  
24       e-mail request to a very long e-mail address. It's  
25       EPA.OPP.regulatoryreform -- that's all one

1 word -- @EPA.gov, EPA.OPP.regulatoryreform@EPA.gov.

2 So, we're going to turn now to our PPDC  
3 members who requested to speak. Actually, the first  
4 PPDC member that requested to speak is Amy Liebman  
5 from the Migrant Clinicians Network. So, Claire, if  
6 you can help us open up Amy's line.

7 MS. ZIMMERMAN: Yes, well, she just  
8 needs -- Amy, if you're on the phone, if you hit pound  
9 6, please.

10 MS. LIEBMAN: I just did. Can you hear me?

11 MS. ZIMMERMAN: Yes.

12 MS. LIEBMAN: Wonderful. You ready for me  
13 to go?

14 MR. KIEGWIN: Okay, you're on the clock.

15 MS. LIEBMAN: Good morning. This is Amy  
16 Liebman. I'm from the Migrant Clinicians Network. I  
17 just wanted to say that I think the EPA has just an  
18 incredible responsibility to protect human health and  
19 the environment. As such, there are numerous  
20 regulations that are critical to the EPA's mission.

21 So, today, as part of the effort to examine  
22 regulations, I want to talk about some important  
23 pesticide regulations. I'm going to address the  
24 importance of the Worker Protection Standard as well

1 as the Certified Pesticide Applicator Rule.

2 First, on both rules, I commend the Agency  
3 for their long and extensive effort to engage  
4 stakeholders as they developed the proposed rule. In  
5 2001, I attended my first stakeholder meeting in  
6 Orlando, Florida. This is one of many, many meetings  
7 that the EPA facilitated across the country to obtain  
8 diverse stakeholder perspectives. These perspectives  
9 were from industry, from farmworker groups, to  
10 clinicians. Their work continued throughout various  
11 administrations.

12 In 2006, I participated in the worker  
13 protection subgroup of the PPDC. Again, this involved  
14 diverse stakeholders. While we often criticize the  
15 EPA for how much time it took to revise the rules, the  
16 result is that we have rules with input from  
17 stakeholders across the spectrum, and it offers  
18 stronger protections to the workers that put the food  
19 on our tables.

20 It's not a perfect rule, and there are many  
21 protections such as cholinesterase monitoring  
22 that the EPA failed to include, but it is important  
23 and a moderate step forward. It is based on science  
24 and evidence-based best practices. There is finally a  
25 much needed minimum age requirement. This is critical

1     for protecting working children. There are more  
2     robust training requirements and notification  
3     processes. And, more importantly, it eases worker and  
4     clinician access to critical life-saving information  
5     about the pesticides used where farmworkers toil to  
6     plant and harvest our food. The certification rule  
7     also offers important clarifications and stronger  
8     protections for worker groups that are likely to be  
9     the most overexposed to pesticides.

10           I expect that all stakeholders in this room  
11     understand the importance of these rules and that  
12     everyone will rally around their implementation. To  
13     weaken or reject these rules is simply unconscionable,  
14     and this will result in a failure of a profound  
15     government responsibility to protect workers.

16           I will remind everyone that these are the  
17     only regulations, the only ones, that protect the most  
18     overexposed worker population of pesticides. And it's  
19     in everyone's best interest that these pesticides are  
20     applied safely as possible, and that workers are  
21     protected. And it is in everyone's best interest that  
22     we move forward with the rules as they stand. Thank  
23     you so much for listening to my comments.

24           MR. KEIGWIN: Thanks, Amy.

25           The next person from the PPDC will be Lori

1 Ann Burd with the Center for Biological Diversity.

2 MS. BURD: We're here to discuss pesticide  
3 regulatory burdens on industry. I want to start by  
4 talking about other burdens, those borne by real  
5 people, not corporations, those who are exposed to  
6 pesticides, for starters, people of color. More than  
7 90 percent of children living in areas of heavy  
8 pesticide use in California are children of color.  
9 What about their burdens?

10 Let's talk about the burdens borne by those  
11 exposed to chlorpyrifos and why Scott Pruitt has  
12 refused to ban it, despite abundant science linking it  
13 to lower IQs, attention deficit disorders, brain  
14 damage, and developmental delays. Over five million  
15 pounds of it are still used each year.

16 How can we ignore the burden of people who  
17 suffer acute poisoning by dangerous organophosphates  
18 like chlorpyrifos? They suffer nausea, confusion,  
19 convulsions, and sometimes death by suffocation. And  
20 what about subacute effects? I'd love to know.

21 When will we sit here and spend the morning  
22 listening to the stories of parents like Magda and  
23 Amilcar Galindo who are raising a child  
24 developmentally disabled, likely as a result of  
25 exposure to chlorpyrifos.



1           When Ms. Galindo was pregnant, she was  
2   living in Salida, California, down the street from  
3   fields where chlorpyrifos was sprayed during her  
4   second trimester. As most of us in this room know,  
5   women who live within a mile of fields where  
6   chlorpyrifos is sprayed during their second trimester  
7   triple their chance of having an autistic child.

8           Her beautiful, tall, lanky 12-year-old Eva  
9   is autistic and has ADHD. Because of Eva's  
10   differences, her classmates are sometimes unkind to  
11   her. Her parents worry about bullying. She has a  
12   hard time with reading and requires help in social  
13   situations.

14           How can we sit here and talk about ways to  
15   make life easier for industry and ignore the burden of  
16   the Galindos and countless other families in  
17   California's central valley who suffer the effects of  
18   exposure to pesticides?

19           When will we bring in the parents, children,  
20   and spouses of those who have lost their battles with  
21   non-Hodgkins lymphoma, a cancer that the World Health  
22   Organization has linked to glyphosate use? When will  
23   these people be asked to share their ideas for  
24   regulations to reduce their burden?

25           Perhaps they would identify regulations and

1 ensure that never again will the chair of a cancer  
2 assessment review from this office promise to, and  
3 apparently achieve success, in killing another  
4 agency's review of a pesticide safety. That's exactly  
5 what Jess Rowland told Monsanto he would do  
6 when the Department of Health and Human Services  
7 indicated interest in reviewing glyphosate.

8           And then, there's the burden of those who  
9 can't speak. Litigation has finally forced this  
10 agency to stop ignoring its legal responsibility to  
11 protect our nation's most imperiled plants and animals  
12 and complete its first ever biological evaluation of  
13 just a few pesticides, including chlorpyrifos.

14           This analysis, on just three of the  
15 thousands of pesticides registered by this office, has  
16 revealed that they're likely to adversely affect  
17 almost all endangered species in this country. Now,  
18 this office is considering requests from Dow and Crop  
19 Life asking it to simply pull the analysis because  
20 they don't like it and refusing to come up with a  
21 schedule for completing consultations for any  
22 pesticides that it doesn't have court enforced  
23 deadlines for.

24           When we will spend a day together in this  
25 room talking about the species who these actions may

1 well drive to extinction? Who here is ready to  
2 declare that they're okay with letting the whooping  
3 crane or Karner blue butterfly or any other species  
4 go extinct? So, yes, please, let's talk about burdens  
5 and regulatory reform.

6 I can talk to you all day about how Section  
7 18 provides a back door for registration of dangerous  
8 pesticides. But really, we need to talk about the  
9 changes that must be made. I can tell you, I lose  
10 zero sleep over the burdens of the pesticide industry,  
11 but I lose lots of sleep over wildlife disappearing  
12 forever because of pesticides that also cause families  
13 like the Galindos to suffer in unimaginable ways.  
14 These are real burdens, matters of life and death.  
15 When we will take the time to discuss how regulatory  
16 reform can help ease these burdens?

17 MR. KEIGWIN: Our next speaker will be  
18 Cheryl Cleveland with BASF.

19 MS.ZIMMERMAN: Or we'll go with Mark.  
20 She's not quite ready yet.

21 MR. KEIGWIN: Okay, Marc Lame with Indiana  
22 University.

23 MR. LAME: Good morning, and may the fourth  
24 be with you. My name is Dr. Marc Lame. I'm an  
25 entomologist and professor at the School of Public

1 Environmental Affairs, SPEA, at Indiana University  
2 where I teach graduate environmental management and  
3 policy. SPEA's graduate environmental program is  
4 ranked number one in the United States. I have been a  
5 FACA appointed member for six years.

6 Tens of thousands of American lives every  
7 year are lost early and unnecessarily to environmental  
8 health hazards. As well, the doctors of our children,  
9 the American Academy of Pediatrics, recognize that  
10 legally used pesticides are detrimental to children's  
11 health. Unfortunately, many public servants,  
12 environmental regulators, are not being allowed or  
13 supported to achieve their mission of protecting human  
14 health and the environment.

15 I believe all Americans can agree that we  
16 want assurance that the water we drink, the air we  
17 breath, the objects we come in contact with, food,  
18 soil, toys, are safe. However, that assurance can  
19 only be given if those assuring the environmental  
20 protection can answer who their clients are. Are they  
21 the pesticide companies and users, a mandate to  
22 regulate, or the public, you, me, and our children?

23 This lack of mission oriented management is  
24 not only a result of strategic ineptitude but of  
25 malice. Administrations opposed to environmental

1 regulations appoint like-minded environmental  
2 administrators who not only ignore their mission and  
3 legal obligation to pursue it, but openly display a  
4 distaste in the disrespect to managers and scientists  
5 who are attempting to protect human health and the  
6 environment.

7           So, reforms that are not needed. To believe  
8 the pesticide regulation should be further relegated  
9 to the states is folly. In the past decade, there has  
10 been an increasing degradation of environmental and  
11 health protection orchestrated by many state appointed  
12 officials. Many of our state environmental agencies  
13 have been drastically downsized, and regulators have  
14 been relegated to act as clerks in state-run permit  
15 shops.

16           To further focus regulatory performance in  
17 how many registrations to pesticide manufacturers are  
18 issued, as opposed to monitoring for compliance and  
19 enforcement, will result in poor water quality,  
20 increased rates of childhood asthma and cancer, as  
21 well as further endangerment of threatened species.

22           Increasing jobs by decreasing environmental  
23 protection with reduced regulation does not work and  
24 is illogical. In fact, most economists recognize that  
25 well-crafted and implemented environmental regulations

1 force countries, as well as industries, to innovate,  
2 yielding a dual benefit of increased efficiency and  
3 increased competitiveness in the market.

4 Reforms that are required. First, help  
5 citizens understand that downsizing of both EPA and  
6 state environmental agencies that paralyze regulatory  
7 function is a bureaucratic disease. It is not only  
8 dangerous in the short run but will take decades to  
9 recover from. Citizens must recognize that rigorously  
10 trained environmental management professionals will  
11 either leave public service or decide not to serve for  
12 the protection of future generations.

13 Second, the Agency's inspector general  
14 should provide increased oversight to EPA regional  
15 offices, assuring that states do not sacrifice  
16 environmental health and that the public is the most  
17 important client of government services.

18 Third, research shows that regulation of  
19 pesticide users is more cost effective when combined  
20 with technical assistance. Thus, any regulatory  
21 reform should include serious robust and significantly  
22 funded technical assistance programs such as  
23 integrated pest management.

24 Fourth, that additional reforms include  
25 increased oversight and state pesticide regulatory

1 agencies and their associations regarding their  
2 relations with those they regulate. Clearly,  
3 associations of regulators should not allow the  
4 appearance of collusion or co-optation to undermine  
5 public health and trust.

6 And finally, fifth, there would be increased  
7 oversight by the Agency's inspector general to ensure  
8 regulated entities cannot directly or indirectly craft  
9 regulations. As the Agency's current administrator  
10 has a history of submitting verbatim comments on  
11 behalf of regulated industries, his office should  
12 receive special attention to avoid conflicts of  
13 interest, including co-optation, collusion, or  
14 corruption. Thank you.

15 MR. KEIGWIN: Liza Fleeson-Trossbach from  
16 Virginia Department of Agriculture.

17 MS. TROSSBACH: Good morning. I'm Liza  
18 Fleeson-Trossbach with the Virginia Department of  
19 Agriculture and Consumer Services. I serve as a PPDC  
20 representative for the Association of American  
21 Pesticide Control Officials, or AAPCO, and I'm making  
22 comments today on their behalf.

23 AAPCO is a national professional association  
24 representing pesticide regulatory officials from the  
25 50 states, tribes, and territories with responsibility

1 for the effective implementation and enforcement of  
2 FIFRA and, as such, are co-regulators with EPA. One  
3 of our key objectives is to engage with the Agency  
4 to ensure workable, effective, and efficient  
5 regulation of pesticides of both the state and federal  
6 level.

7 While supporting the goal of the recent  
8 revisions to the Worker Protection Standard and the  
9 pesticide applicator certification rule, we do have  
10 concerns for states, specifically implementation time  
11 lines, resource demands, and the development of  
12 compliance materials.

13 AAPCO acknowledges and appreciates the  
14 Agency's consideration of the many concerns expressed  
15 by states. However, they believe further  
16 modifications would be beneficial to states and the  
17 regulated industry while still being protective of  
18 human health and the environment.

19 AAPCO supports the delayed implementation of  
20 WPS to allow time for meaningful outreach and  
21 education, as well as the delayed implementation of  
22 the certification rule to allow specific issues to be  
23 addressed.

24 AAPCO firmly believes the NPDES pesticide  
25 general permit requirements are duplicative of federal



1 pesticide registration requirements without providing  
2 additional tangible water quality protections and  
3 should be repealed.

4 In 1996, the Agency exempted minimum risk  
5 pesticides from product registration in order to  
6 reduce cost and regulatory burdens. This exemption  
7 shifted costs and the regulatory burdens to state lead  
8 agencies, many of which require state registration of  
9 products.

10 States are finding more products in the  
11 marketplace which do not meet the federal requirements  
12 for the exemption from registration. But, due to low  
13 priority assigned by the Agency for violations of  
14 appropriate and timely action by the Agency, it's not  
15 pursued. The exemption should either be repealed or  
16 the Agency should place a higher priority on products  
17 which do not meet the requirements for this exemption.

18 With the proposed reductions to EPA budget,  
19 AAPCO would be amiss if it did not offer that any  
20 reductions to the state tribal assistance grants will  
21 make it difficult, if not impossible, for states to  
22 continue enforcement of FIFRA. States have  
23 historically had to work with increasing mandates  
24 under reduced STAG funding available for pesticide  
25 programs cooperative agreements. Should there be

1 additional reductions to STAG funds, states would be  
2 faced with limiting participation or, in some cases,  
3 returning regulatory responsibilities to the Agency.

4 AAPCO fully supports EPA in their efforts  
5 towards the development and utilization of technology  
6 in the pesticide registration, state grant reporting,  
7 and enforcement tracking processes, and dedicating  
8 resources to fund these efforts. The implementation  
9 of technology will increase efficiencies, provide for  
10 more consistency in data collection, and enhance  
11 reporting capabilities and information exchange  
12 between states and EPA.

13 Finally, AAPCO would also like to express  
14 our support for and the importance of continued  
15 funding for the Pesticide Regulatory Education  
16 Program, or PREP, the Pesticide Inspector Residential  
17 Training program, PIRT, and the State FIFRA Issues  
18 Research and Evaluation Group. Each of these has  
19 contributed to improving regulatory decisions,  
20 priorities, and program implementation, for example,  
21 the development and implementation of performance  
22 measures for the enforcement program.

23 PREP, PIRT, And SFIREG provide an  
24 opportunity to increase the depth of understanding and  
25 consistency and implementation of FIFRA for both state

1 and EPA carrying out the pesticide program objectives.  
2 AAPCO will provide detailed comments to the docket to  
3 address these and other items and appreciates the  
4 opportunity to comment today.

5 MR. KEIGWIN: Gabrielle Ludwig with the  
6 Almond Board of California.

7 MS. LUDWIG: So, Gabrielle Ludwig with the  
8 Almond Board of California. The comments I'm making  
9 are on behalf of the Almond Alliance, an almond  
10 voluntary grower and handler association. I'm also a  
11 six-year member of the PPDC.

12 From a grower's perspective, one of the  
13 things we need to note is we need a credible,  
14 efficient, science-based, and transparent Office of  
15 Pesticide Programs process to assess the potential  
16 risks and benefits to society of the use of pesticides  
17 and to register the uses where appropriate. We do not  
18 want to see actions that undermine the credibility of  
19 the OPP.

20 A couple of sort of overarching comments on  
21 issues we see, we do think that we need some review of  
22 the water modeling, just in the last six months. For  
23 the Almond Alliance, we have submitted comments on  
24 around 10 active ingredients. The one issue in  
25 comments have been concerns about pesticides in water.

1  
2           We want to suggest that a process be  
3 developed for collaborative review of the models and  
4 assumptions that go into the calculations for the  
5 potential for a pesticide to make it into surface  
6 water and the possibility into drinking water and/or  
7 affect aquatic species.

8           From what we can tell of the grower group,  
9 there are several assumptions that could possibly be  
10 refined. The main one from our perspective is when it  
11 is or is not appropriate to use the spray drift factor  
12 from young dormant trees. Another one is timing of  
13 applications versus the chances of rainfall. That's  
14 certainly relevant to California conditions.

15           There may also be opportunities to see  
16 confined ways to develop more regionalized models or  
17 new or less deterministic approaches. In the process,  
18 maybe sort out a better way to develop monitoring data  
19 to help define the models. So, to improve  
20 efficiencies, step back to publicly review and assess  
21 what options for refining the water, drift, runoff  
22 calculations exist.

23           The next one is complying with Endangered  
24 Species Act. It is clear that the intense efforts by  
25 both OPP and the Services to develop processes to

1     comply with the Endangered Species Act are simply  
2     still too cumbersome. We've done it and are taking up  
3     more resources than the agencies have.

4             Let's suggest revisiting the efforts to  
5     develop counterpart regulations to streamline the  
6     process. Fundamentally, OPP has the knowledge as to  
7     how pesticides behave in the environment and to  
8     conduct pesticide risk assessments, which the Services  
9     do not, and certainly do not have enough expertise to  
10    keep up with the constant stream of regulatory  
11    decisions by OPP.

12            Similarly, the Services have the knowledge  
13    of the species and habitat requirements. It doesn't  
14    make sense -- so, therefore, you know, we basically  
15    say let's step back and see how that can be made more  
16    efficient. For those of you who do care deeply about  
17    the Endangered Species Act, you realize it's exactly  
18    these frustrations that call for the complete overhaul  
19    of ESA. So, I think working together on this one  
20    would be wise.

21            Another area is just continued engagement on  
22    international -- participating in various  
23    international activities. This came up yesterday at  
24    the PPDC meeting, whether you're looking at the  
25    biopesticides, the use of new testing methods, and so

1     forth. I just wanted to say that we really think that  
2     there's a lot of opportunities for harmonization.  
3     Both previous administrations and this administration  
4     say that they want to increase agricultural exports.  
5     We need help in that arena. But again, it goes beyond  
6     just the MRL issues. It really gets into the  
7     methodologies and so forth.

8             One thing to realize there's an opportunity  
9     for some extra training, there's an extraordinary JMPR  
10    session coming up in the spring of 2019. That might  
11    be a great opportunity to expose some new people from  
12    OPP to that process.

13            And then the third one is just from the  
14    Office of Research and Development, just to ensure  
15    that any efforts by the Office of Research and  
16    Development are meaningful to the regulatory sister  
17    offices within EPA. Similarly, any efforts to conduct  
18    research on pesticides affects the other government  
19    agencies, such as USDA/ARS, are funded by USDA and NIFA,  
20    should require engagement with OPP staff prior to  
21    embarking on the research to ensure that the research  
22    will be relevant and useful to OPP.

23            Research that meets regulatory needs is not  
24    the same as research for research's sake. The vast  
25    majority of pesticide related research is not usable

1 in the regulatory processes and sometimes can even  
2 help inform the process, thus requiring US government  
3 agencies that conduct research related to pesticides  
4 consult with OPP would help to ensure that more of  
5 the research would truly help clarify when and when  
6 not pesticides have unintended consequences.

7 MR. FREDERICKS: My name is Jim Fredericks.  
8 I'm with the National Pest Management Association. I  
9 thank you for the opportunity to make some comments  
10 this morning. I have four brief comments.

11 First of all, by way of introduction, the  
12 National Pest Management Association is the only  
13 national organization representing the structural pest  
14 management industry. NPMA's members protect public  
15 health and property in countless homes, businesses,  
16 and public buildings across the United States.

17 First, we encourage the Agency to carefully  
18 consider the benefits of pest control tools during  
19 their registration and registration review process,  
20 including use patterns that are specifically for  
21 nonagricultural users.

22 Regarding protecting endangered species, we  
23 encourage the EPA and the Services to develop a more  
24 efficient and less bureaucratic process to make  
25 decisions regarding endangered species, developing a

1     smarter way to allocate resources to protect our  
2     nation's environment.

3             Thirdly, NPMA applauds the Agency on the  
4     significant improvements made to the final rule for  
5     certification of pesticide applicators, ensuring  
6     proper training. The efforts taken by the EPA to  
7     consider concerns from stakeholders in crafting the  
8     final rule was a model for how the process should  
9     work.

10            And finally, NPMA encourages EPA to engage  
11    user groups and stakeholders to help make pesticide  
12    labels easier to use and understand, streamlining the  
13    cumbersome label language that users must read, use,  
14    follow, and understand to ensure safe and effective  
15    use.

16            NPMA will be submitting full written  
17    comments to flesh out some of these points. Thanks.

18            MR. KEIGWIN: Cheryl Cleveland with BASF.

19            MS. CLEVELAND: Thank you. So, I am also an  
20    exiting six-year tenured member of the PPDC. I've  
21    really been honored to be part of this process. It's  
22    given me great insight as to all the issues and  
23    complexity that you as servants for our government  
24    face.

25            I want to focus on the fact that the



1 executive order that we're responding to also includes  
2 modifications. I can't speak to the specifics of the  
3 rules and regulations that you need, but I would like  
4 to speak to the priorities that you will need to think  
5 about as you review your own internal system.

6           It's my understanding that the Office of  
7 Pesticide Programs exists because pesticides are  
8 proven useful tools to protect crops, increase yield,  
9 and thereby significantly contribute to a global food  
10 supply that is low cost and abundant. But there is  
11 also a need for rigorous data review and processes in  
12 place that balance food security along with food  
13 safety.

14           So, I would suggest that from my  
15 perspective, there are three areas that have some  
16 barriers to best achieving some of that. I've watched  
17 over the six years here in discussions. There's  
18 something in the way of data management. As much as  
19 you try to be transparent, there's rules and  
20 regulations, and there's IT contracts, and there's  
21 stuff that isn't helpful.

22           And even though the things that we discussed  
23 yesterday in trying to get through a new data  
24 reporting process, there was a focus on data elements,  
25 and there wasn't the ability to talk across the whole

1 process. Similarly, the SmartLabel idea is a great  
2 idea at a high level, but there's something getting in  
3 the way of its best implementation. So, I don't know  
4 what the government needs to do to remove that, but  
5 that's something that needs to be streamlined and  
6 thought about.

7           The second thing that I would ask you to  
8 focus on is the use of real world monitoring  
9 information to help incorporate for refined risk  
10 assessment. We see that need in the ESA model that  
11 let's through 97 percent of things. We see that need  
12 in the water modeling that continues to focus on  
13 models instead of real world data. I think that's a  
14 real need to continue to vet precise models against  
15 real world information.

16           The third thing, and I want to combine this  
17 with also the executive order where there was the  
18 promoting agricultural and rural prosperity in  
19 America. One of the points there was to encourage the  
20 production in exports and the use of domestically  
21 produced agricultural products.

22           There's a desperate need for international  
23 engagement, because you can't export products --  
24 growers can't use them in the US no matter how  
25 rigorous and wonderful we set up our tolerances and

1 MRLs -- if you have other countries that won't  
2 establish the same MRLs for export.

3 And the EU is tremendously engaged at the  
4 international level and they're promulgating their  
5 hazard cutoffs. We have other countries that only  
6 have the ability to use screening models. Without  
7 understanding the data rich information on the  
8 consumption side as well as the models, there's a hole  
9 left. That would be very useful for the US  
10 participation as well.

11 MR. KEIGWIN: Thank you.

12 Our next speaker will be Komal Jain from the  
13 American Chemistry Council.

14 MS. JAIN: Good morning. My name is Komal  
15 Jain. I'm the Executive Director of the Biocides  
16 Panel of the American Chemistry Council. Thank you  
17 for the opportunity to provide oral comments on  
18 regulatory reform as it relates to the pesticides  
19 program.

20 Let me note up front that I do not represent  
21 the agriculture community. I represent the  
22 antimicrobial or biocides industry, and our  
23 applications consist of material preservation, water  
24 treatment, antifouling, and controlling of pathogens  
25 and processing through facilities and hospitals.

1           The Biocides Panel will be submitting  
2     detailed written comments. So, given my time  
3     allotment, I am going to highlight only two areas of  
4     likely several areas where reform and clarity could  
5     improve outcomes for both the Agency and the  
6     registrants.

7           We greatly support and appreciate the work  
8     of OPP and AD. We recognize their time and resources  
9     are not infinite, and, thus, we are looking for ways  
10    there can be greater efficiencies. As an example,  
11    there are opportunities for EPA and FDA to reduce  
12    their duplication of work. When EPA and FDA have  
13    standards that are similarly close or sufficiently  
14    close, FDA and EPA could cut down on bureaucracy and  
15    needless duplications by recognizing each other's  
16    reviews.

17          For example, certain food additives are  
18    regulated by FDA and EPA. And even though substances  
19    are approved by FDA by a food contact notification,  
20    EPA may also conduct a risk assessment of those  
21    substances already approved by FDA. Rather than  
22    having agencies review the same substances, EPA could  
23    avoid duplication of work and the potential for  
24    conflicting risk assessments by accepting the review  
25    of FDA. Statutory obligations and implementing

1 regulatory rules need to be assessed to see what can  
2 be modified or rescinded. Other tools such as MOUs  
3 could possibly be employed.

4 The second theme I want to point out is  
5 implementation of procedures, and particularly  
6 notification procedures, so that they are fully  
7 recognized by EPA. Under the regulations, any  
8 modifications to the composition, labeling, or  
9 packaging of a registered product can only be  
10 submitted through the amended registration process.  
11 That also includes the PRIA fee.

12 However, there is another section of the  
13 regulations that allows minor changes to be made  
14 through notification or non-notification. The stated  
15 intent is to streamline and accelerate many minor  
16 changes that could be determined to have no potential  
17 to cause unreasonable adverse effects. To implement  
18 that regulation, EPA issued PR notices, the most  
19 current being PR 98-10. It contains specific time  
20 lines for informing registrants if the notification  
21 has been rejected.

22 For antimicrobial registration, the  
23 requirement is that the Agency respond within 30 days,  
24 along with the reasons. However, registrants are not  
25 receiving those decisions within 30 days, particularly

1       disapprovals. It's more in the 90-day time frame.

2               And even when submissions fully comply with  
3       the requirements of 98-10, the Agency has rejected the  
4       notification and required submission for amended  
5       registration. That's dismissing the value of the  
6       notification process and their own regulations. This  
7       puts an unnecessary regulatory burden on both  
8       registrants and the Agency. The notification  
9       requirement should be revisited under both regulation  
10      and PR notices, or PR 98-10, and clarity should be  
11      provided through regulations or implementing  
12      guidelines.

13              Again, these are only two areas of several  
14      that the Biocide Panel plans on discussing or  
15      commenting on. And again, I thank you for your  
16      attention.

17              MR. KEIGWIN: Our next speaker will be Pat  
18      Bishop with People for the Ethical Treatment of  
19      Animals.

20              MS. BISHOP: Hi, I'm Pat Bishop. I'm with  
21      PETA and representing the animal welfare community  
22      which advocates for the replacement and reduction of  
23      animals used in regulatory testing and use of more  
24      human relevant approaches.

25              So, one of the areas we'd like EPA to look

1 at as part of this regulatory reform is to conduct  
2 some systematic reviews of toxicology tests required  
3 under Part 158 of Data Requirements for Pesticide  
4 Registration. These tests use thousands of animals to  
5 test a single pesticide active ingredient. The test  
6 requirements for both human health effects and  
7 ecotoxicity have been in place for decades but have  
8 rarely been reviewed with respect to the information  
9 they supply for risk assessment and setting exposure  
10 limits.

11           Efforts should be initiated to  
12 retrospectively examine how the data have been  
13 historically used and which tests might be identified  
14 that provide little or no value in setting pesticide  
15 exposure when it's in risk assessment.

16           In a few cases where this has already been  
17 done, EPA was able to eliminate test requirements or  
18 provide guidance for waivers. A prime example is a  
19 one-year chronic test in dogs which had been required  
20 for years along with the 90-day subchronic dog test.  
21 A thorough retrospective review clearly showed that  
22 the chronic test offered little additional value when  
23 the 90-day was available.

24           Accordingly, EPA eliminated the requirements  
25 of the chronic dog test in 2007. With respect to the

1 90-day, there are some researchers now that are saying  
2 that the regulatory needs for this study may not be  
3 needed any longer, as other techniques may be applied  
4 to the 90-day study in rats.

5 Yesterday, we discussed the acute thermal  
6 toxicity data and the waiver that has been issued.  
7 Again, we encourage EPA to look at some of the work  
8 that Health Canada has done and see if that waiver  
9 could also be applied to the active ingredients.

10 Another area which we also discussed  
11 yesterday was again GHS, looking at that and hopefully  
12 transitioning to that to avoid having two systems in  
13 use for industry.

14 And finally, we would also encourage EPA to  
15 again look at Part 158 and perhaps add a statement  
16 that would require that non-animal methods of toxicity  
17 testing be used if they are available and accepted by  
18 OPP. Thank you.

19 MR. KEIGWIN: Thanks, Pat.

20 Our next speaker is Virginia Ruiz with  
21 Farmworker Justice.

22 MS. RUIZ: Good morning. My name is  
23 Virginia Ruiz. I'm the Director of Occupational and  
24 Environmental Health at Farmworker Justice.  
25 Farmworker Justice is a national organization that



1 strives to improve the living and working conditions  
2 of farmworkers in the United States. I have been a  
3 PPDC member for six years, and I'd like to thank EPA  
4 for the opportunity to participate in these dialogues  
5 and to speak this morning.

6 I just wanted to say that I reject the  
7 premise that rules and regulations that protect human  
8 health and the environment are a burden to any  
9 individual or industry. Without common sense federal  
10 rules, like the recently revised Worker Protection  
11 Standard and Certification of Pesticide Applicator  
12 rules, the burdens of illness and injury from  
13 pesticide poisonings, medical care, missed work days,  
14 and environmental contamination would fall on those  
15 who can least afford it, pesticide handlers, workers,  
16 and agricultural fields, orchards, greenhouses, and  
17 their children.

18 These regulations call for basic preventive  
19 measures that will save millions of dollars in medical  
20 costs and lost productivity due to illness. Employers  
21 who strive to promote a culture of safety in the work  
22 places already implement these common sense measures,  
23 and some even go beyond measures, like annual basic  
24 safety training, posting of information, meaningful  
25 hazard communication, functioning personal protective

1 equipment, adequate supervision, and prohibiting  
2 children from handling pesticides.

3 EPA developed these regulations after  
4 decades of complication with all stakeholders,  
5 including laborers, employers, state agencies, public  
6 health professionals, and educators. Many states are  
7 already successfully implementing revisions to the  
8 Worker Protection Standard.

9 Efforts to delay, modify, or rescind the WPS  
10 and Certified Pesticide Applicator rule are an affront  
11 to those who served in some previous administrations  
12 at EPA who actually did listen to all stakeholders and  
13 an insult to those who have worked for years to move  
14 forward on occupational safety and agriculture and to  
15 the men, women, and children who benefit from safe  
16 working conditions and a clean environment. Thank  
17 you.

18 MR. KEIGWIN: Our next speaker will be  
19 Cynthia Palmer with the American Bird Conservancy.

20 MS. PALMER: Thank you. I'm Cynthia Palmer.  
21 I'm Director of Pesticides Science and Regulations for  
22 the American Bird Conservancy.

23 I just returned from the gymnastics national  
24 championship in Michigan watching my child compete her  
25 double flips and other tricks. If these flips go just

1 millimeters off track, these young athletes risk  
2 concussions. So, there are crash pads everywhere.

3           The American bald eagle and other raptors,  
4 we see this same combination of power, grace, and  
5 honorability. The eagles can fly 10,000 feet in the  
6 air and can dive a 100 miles per hour. Yet, one meal  
7 of a brodifacoum-laced rat is enough to  
8 cause death from internal bleeding.

9           Our nation does great things, but we need  
10 our crash pads, our safeguards for the times when  
11 things go slightly off track, our protection from the  
12 pesticides that throw off the arctic tern's navigational  
13 systems on their 44,000 mile annual trek, and that  
14 cause our children's IQs to plunge.

15           EPA scientists work tirelessly to study the  
16 impacts of pesticides and to develop the regulations  
17 needed to keep us safe. A single regulation can take  
18 years of tedious hard work by EPA scientists and by  
19 stakeholders. To dismantle these safeguards make  
20 sense only if EPA no longer cares about health and  
21 safety.

22           EPA desires more litigation, as evidenced in  
23 ignoring the science on chlorpyrifos, or EPA prefers  
24 to squander the nation's resources by relegating to 50  
25 state governments the work that can and should be done

1 cost effectively by pesticide experts here at EPA.

2 The wealthy may be able to buy themselves out of some  
3 dangers with bottled water, organic food, and  
4 carefully chosen neighborhoods, but regular people can  
5 seldom afford to do so.

6 Looking at the official list of questions, I  
7 can only conclude they're the wrong ones to be asking.  
8 That said, as the Agency moves to electronic reporting  
9 for FIFRA 6(a)2, which, of course, makes sense for the  
10 sake of trees and efficiency, please also fix the  
11 glaring deficiencies outlined in our rule making  
12 petition, in particular, the unrealistically high  
13 numbers of dead animals needed to trigger incident  
14 reporting requirements.

15 Under the current regs, pesticide  
16 registrants are not required to report wildlife kills  
17 unless they involve 1,000 of a schooling species of  
18 fish, 50 herding mammals, 5 raptors, or 200 of a  
19 so-called flocking species of birds, and also  
20 problematically fix the lack of public access to  
21 incident reporting data without time and resource  
22 intensive FOIA requests. Deaths of frogs or owls  
23 should not be treated as state secrets. Thank you.

24 MR. KEIGWIN: Our next speaker is Nina  
25 Wilson on behalf of the Biopesticide Industry

1 Alliance.

2 MS. WILSON: Thank you. Thank you for the  
3 opportunity to comment. I'm not coordinated enough to  
4 stand and read my notes at the same time, so I'll sit.

5 BPIA is the Biological Products Industry  
6 Alliance, and we are a national trade organization of  
7 producers of biopesticides and biostimulants. These  
8 are low risk tools that are designed for use in both  
9 the organic and also the conventional ag and non-ag  
10 markets. Our members rely on a predictable science-  
11 based risk assessment process where the requirements  
12 are commensurate with these low risk products.

13 As an example, for EPA knows this well, if I  
14 call acetic acid a pesticide, it is subject to all the  
15 requirements of FIFRA, just like any other pesticide  
16 would be. However, when I go home, I call acetic acid  
17 vinegar, and I use it liberally over my salads.

18 We appreciate having continued dialogue with  
19 EPA on the existing emerging issues in this very  
20 rapidly growing market. Generally, we don't believe  
21 added regulations is needed, but clarification around  
22 the working definition of a biostimulant is something  
23 that we are looking forward to. We're looking forward  
24 to the comment period and the publication of that  
25 document.

1           EPA's current risk assessment, and in  
2     particularly BPPD, these are a stand-alone group of  
3     people who register products, the Biopesticide and  
4     Pollution Prevention Division, their global model for  
5     low risk regulation. We do want to make sure that  
6     increased and unnecessary interpretation of the  
7     existing regulations do not stifle innovation and is an  
8     option of these lower risk products. We do support  
9     EPA, specifically BPPD, in having resources to help  
10    bring our lower risk products to market.

11           MR. KEIGWIN: Our next speaker is Dan Kunkel  
12    with IR-4.

13           MR. KUNKEL: Thank you. I'm with the IR-4  
14    program. We are a publicly sponsored program. Our  
15    headquarters is at Rutgers University. We're  
16    sponsored primarily by the USDA to generate data and  
17    make regulatory submissions to EPA. We make  
18    submissions to the Registration Division, PRD, and  
19    also Biopesticide Pollution Prevention Division as  
20    well.

21           We make these submissions in support of pest  
22    control products for specialty crop growers, and we've  
23    had a longstanding partnership with the Agency in  
24    continuing to effectively address grower pest control  
25    needs, especially crop grower needs.

1           While it may be difficult at times for IR-4  
2   to adopt new submission requirements that are often  
3   added in response to new regulations, such as the  
4   preliminary risk assessments with FQPA, then exemption  
5   justifications for PRIA, we have been able to adapt  
6   with the support from registrants in EPA. We feel  
7   that the new electronic submission portal has been a  
8   significant improvement. In our view and in our work,  
9   we feel that the Agency has essentially made a  
10  complete transition to electronic reporting.

11           There can be some regulatory review  
12  redundancies when adding specialty crops to already  
13  registered products, especially when new  
14  considerations come into play that can delay  
15  registration of minor uses. These are uses that are  
16  grown on limited acreage. So, we continue  
17  consideration reevaluation of the various tools used  
18  for risk assessment. It may help to streamline the  
19  process when adding some of these minor uses and make  
20  the process less burdensome for EPA and the data  
21  generators that provide these products to growers.

22           Finally, IR-4 and the specialty crop growers  
23  appreciate the hard work and dedication of OPP staff  
24  that continues to provide growers with access to the  
25  latest technology that's so important to pest control,

1 especially considering invasive pests, pesticide  
2 resistance, and often these new products are very  
3 important and fit well into IPM programs.

4 In 2016, EPA established more than 150  
5 tolerance submissions based on IR-4 data and also  
6 registered 4 new biological products, biopesticide  
7 products, that the specialty crop growers can now use.  
8 So, thank you.

9 MR. KEIGWIN: Our next speaker is Nichelle  
10 Harriott from Beyond Pesticides.

11 MS. HARRIOTT: Hello, good morning. My name  
12 is Nichelle Harriott. I represent Beyond Pesticides.  
13 Thank you for the opportunity to comment.

14 Under FIFRA, EPA has the responsibility to  
15 ensure that pesticide substances do not pose  
16 unreasonable risk to human health or the environment.  
17 The regulations and safeguards set up by FIFRA are  
18 necessary to ensure the safety of people and the  
19 environment from hazardous pesticides.

20 Recent efforts by EPA to address children's  
21 exposure to the neuro-toxic pesticide chlorpyrifos and  
22 the subsequent failure of the Agency to move forward  
23 with its proposed restriction of the chemical  
24 demonstrates that the safeguards defined under FIFRA  
25 are often ignored. This puts children and vulnerable



1 farmworker communities at risk and must not be allowed  
2 to continue.

3 The Agency is asking for which regulatory  
4 provisions should be repealed, replaced, or modified.  
5 We insist that current regulations under the Office of  
6 Pesticide Programs are necessary for protecting human  
7 and environmental health and must be improved.

8 The pesticide registration program is  
9 intended to ensure that pesticides meet safety  
10 standards before they are used or sold. To improve  
11 this program, EPA should not allow pesticide  
12 registration and use without a full understanding of  
13 all the potential risks to the public and to non-  
14 target organisms.

15 Data gaps continue to plague the Agency, and  
16 EPA must refuse registration requests if all the  
17 required information to conduct a comprehensive safety  
18 review is not provided. Data gaps still exist for  
19 chemicals that have been on the market for years but  
20 (inaudible) through their registration review cycle,  
21 and outstanding studies are still awaiting submission.  
22 This means that the conditional registration  
23 protection under FIFRA Section (3)(e)(7) should be  
24 disallowed.

25 Incident reporting is a useful tool that

1 helps the Agency run concise risk management  
2 conclusions with real world events. Currently,  
3 Section 6(a)(2) of FIFRA allows manufacturers to submit  
4 incident reports to EPA as a mechanism for which these  
5 incident reports can be made is inadequate. Threshold  
6 numbers that trigger reporting requirements for non-  
7 target species are extraordinarily high, arbitrary,  
8 and not supported by scientific or biological reasons.  
9 These thresholds should be disallowed.

10 EPA is asking us to reduce regulatory  
11 burdens regarding reporting requirements, including  
12 reducing the frequency of reporting. However,  
13 reducing regulatory burdens should not be done at the  
14 expense of public health or the environment.  
15 Currently, industry bears the burden of reporting  
16 incidents under Section 6(a)(2), and that burden should be  
17 theirs to bear, as it is their registered products that  
18 are involved in the reported incident.

19 Frequency in reporting is the result of  
20 frequency in harms being inflicted on non-target  
21 species. These incidents come about as a result of  
22 poorly regulated products, unclear labels leading to  
23 misuse and a general lack of understanding of the  
24 potential hazards of pesticide exposures due to the  
25 allowance of outstanding data gaps and assumed risks.

1           If EPA wants to reform how they conduct risk  
2     assessments and refuse to register products that have  
3     the potential to pose harm to non-target species, then  
4     there will be no need for burdensome or frequent  
5     incident reporting.

6           Lastly, there are many important programs  
7     overseen by OPP that we hope would not suffer from  
8     unjust regulatory reform as a means for industry  
9     to share commitments that adhere to federal laws and  
10    safeguard public and environmental health from the  
11    pesticides they market. These include EPA's  
12    pollinator protection program, the endocrine  
13    disruption screening program, worker protection  
14    initiatives, and the consultation process for the  
15    endangered species protection program.

16           We believe these programs are critical to  
17    improving our understanding of pesticide hazards and  
18    exposures and help the Agency refine its risk  
19    assessment methodologies. Although these may be  
20    difficult decisions for the Agency, we urge  
21    prioritizing protections for human and environmental  
22    health as mandated by FIFRA so that the Agency does  
23    not lose sight of its mission and purpose. Thank you.

24           MR. KEIGWIN: Our next speaker will be  
25    Sheryl Kunickis with the U.S. Department of Agriculture.

1 MS. KUNICKIS: Thank you very much. My name  
2 is Sheryl Kunickis. I'm the Director in the USDA  
3 Office of Pest Management Policy. I just want to  
4 thank EPA for the opportunity to be a part of this  
5 meeting today. It's very, very important.

6 At the end of the day, pesticide regulation  
7 is about farmers having the tools they need to achieve  
8 food security. That is the bottom line. So, I just  
9 have a few comments. I want to keep within the three  
10 minutes.

11 First of all, USDA supports revisions to the  
12 worker protection standards, including the designated  
13 representative provision, the application exclusion  
14 zone, and the definition of a farm family, which is  
15 defined a little differently by EPA.

16 EPA has a request from our partners at the  
17 National Association of State Departments of  
18 Agriculture and from the American Farm Bureau  
19 Federation, asking for a delay in implementation of  
20 the Worker Protection Standard final rule. USDA  
21 supports that delay and welcomes the opportunity to  
22 work with EPA and other stakeholders to revise that  
23 rule.

24 USDA applauds EPA for reducing the burden  
25 associated with the certification and training rule

1 making effort which aims to increase certification and  
2 training requirements for certified applicators of  
3 restricted use pesticides. However, USDA is not  
4 confident that these new federal regulations will  
5 result in significant benefits in terms of reducing  
6 risks to applicators.

7 It is clear that through the implementation  
8 of this rule, it will be costly for states, tribes,  
9 and other certifying entities, as well as for  
10 applicators and farm owners. USDA also supports the  
11 delay requested by NASDA.

12 On the Endangered Species Act on pesticides, USDA  
13 supports EPA stepping back from the current mammoth process  
14 that's being developed in order to reevaluate and forge a  
15 more reasonable path forward. USDA genuinely appreciates  
16 EPA's efforts in the process, but the outcomes of the current  
17 interim approaches are troubling to the agricultural community.

18 USDA has voiced strong opinions regarding  
19 blanket proposals restricting tank mixes unless  
20 scientific evidence points otherwise. This will  
21 result in serious effects for growers and issues for  
22 growers and has the potential for a domino effect.

23 If efficacy is impacted by restrictions,

1 we may see more resistance and subsequently lower  
2 yields and less food. The restrictions will increase  
3 the number of trips across the fields affecting soil  
4 compaction, fuel use, safety for workers, and the  
5 potential for off-target impacts.

6           USDA is very concerned that multiple  
7 alternative active ingredients are being mitigated  
8 simultaneously with benefits assessments for one AI or  
9 active ingredient assuming that an alternate active  
10 ingredient will be available, even though the  
11 alternative active ingredient is also being mitigated.  
12 We're unaware of examples of going back to unmitigated  
13 chemical and thus, we could be left with resistance  
14 issues and fewer alternatives to combat wheat, insect  
15 pests, and diseases.

16           Then, lastly, numerous stakeholders,  
17 including some of EPA's scientific advisory panel and  
18 USDA, requested that EPA seek public comment to  
19 finalize their 2010 framework for incorporating human  
20 epidemiologic and incident data in risk assessments  
21 for pesticides before using it in regulatory work. We  
22 learned it was posted without comment or notice in  
23 December of 2016.

24           Because epidemiological studies have an  
25 important role, we would like to understand how this

1 framework will be used in regulatory decisions. If  
2 it's likely to alter EPA's analysis of epidemiological  
3 studies to change what is required of registrants or  
4 to be used as a justification for any regulatory  
5 actions, we request that the framework be subject to  
6 public review and comments.

7 We would also like EPA to reconsider  
8 subjecting any risk assessments that relied on the  
9 draft framework to re-review and additional public  
10 comment. USDA looks forward to continuing to work  
11 with EPA as we have in the past on all future  
12 endeavors. Thank you so much.

13 MR. KEIGWIN: Our next speaker will be Donnie  
14 Taylor with the Agricultural Retailers Association.

15 MR. TAYLOR: Thank you. I'm going to stay  
16 seated because if I stand up, the view in this area is  
17 not very effective, so I'll stay where I am.

18 Also, I'd like to thank everybody at EPA. I  
19 know you're all very hard working people. I know you  
20 have a cross section of this country that represents  
21 all the views that are being represented here. We  
22 appreciate that. We know you're mothers, and fathers,  
23 and daughters, and sons, so we know you have the same  
24 concerns we do. So, thank you for your efforts.

25 I'm Donnie Taylor. I'm with the Ag Retailers

1 Association. I'm representing them today, I'm  
2 representing my family today, and I'm representing my  
3 history of being born and raised on a farm today. So,  
4 that's what I'm representing.

5 We'll start off with ARA. We're the  
6 nation's agricultural retailers and distributors  
7 association, also referred to as the farmer's supply  
8 dealers. How many of you remember the Dodge truck  
9 commercial? Paul Harvey "gotta be a farmer" during  
10 Super Bowl? Oh, come on. That's who we service. So,  
11 that's the people that we provide products and  
12 services to.

13 So, these people are located throughout the  
14 United States, range in size from local family held  
15 businesses, farmer cooperatives that are local, to  
16 large companies with multiple outlets. We play an  
17 important role in providing farmers with essential  
18 crop input products. Our industry is a cooperating  
19 partner in the regulated community and fully  
20 understands the importance of chemical safety as well  
21 as security.

22 So, ARA members engage in communication,  
23 engage their employees and local first responders and the  
24 the community to enhance environmental, health,  
25 safety, and security matters. They are very active



1 and love their local communities.

2 So, ARA supports EPA. We've tried to work  
3 jointly with EPA as far as compliance and regulations  
4 are concerned. We recently worked on a brochure  
5 together on choosing the right herbicide. So, we're  
6 all about education and compliance. When regulations  
7 come in place, we know we ask a lot of stupid  
8 questions with a lot of stupid detail, but, in  
9 actuality, we're trying to make sure that we're in  
10 compliance and we communicate that message of  
11 compliance to our members.

12 So, as far as things to think about, you've  
13 got a lot on your plate. Your budget constrained as  
14 well. But we can do a FIFRA, go back to the basics,  
15 if we can eliminate some duplications that occur out  
16 here in the marketplace, be sensitive to the cost  
17 versus benefit ratio, particularly for those small  
18 business owners that we represent, and we appreciate  
19 the partnership that we have.

20 So, the last question. I like to end with  
21 questions. How many of you here live on a farm or were  
22 born and raised on a farm? How many of you plan on  
23 eating today? I think that's why we created the  
24 community, to bring those two groups a lot closer  
25 together. So, my last parting words are, if you have

1 an opportunity, hug a farmer today.

2 MR. KEIGWIN: Our next speaker is Allen  
3 McLaurin with the National Cotton Council.

4 MR. McLAURIN: Thank you, Rick. My name is  
5 Allen McLaurin. I represent the National Cotton  
6 Council who represents the cotton industry throughout  
7 the United States. But actually, I'm a farmer. I'm  
8 probably the only farmer in the room, and I'll be  
9 standing outside after the meeting if you want to come  
10 hug me. So, I'll be there.

11 Anyway, we have a couple of concerns. One that  
12 Sheryl mentioned is the language in the worker  
13 protection standards, the designated representative  
14 language of the role needs to be removed. This opens  
15 up producers to serious privacy, confidentiality  
16 information regarding the business and security  
17 issues.

18 Also, under conflicting messages to  
19 producers, the Agency has lost consistency of messages  
20 to regulatory process. On one hand, the Agency talks  
21 about pollinator habitat around fields. But, on the  
22 other, the Agency tells the producers to keep the  
23 fields mowed and free of wheat for resistance  
24 management. So, we're just asking for a little  
25 consistency in the language.

1           I'm going to stick myself out on a limb,  
2 Rick, and thank you and EPA staff and the PPDC committee  
3 for bringing this group together as you have for many  
4 years and listening to different sides. You all have  
5 a tough job, and it really makes me proud to be a  
6 farmer in the southern part of North Carolina every  
7 time I come up here. You all do a great job. Thanks.

8           MR. KEIGWIN: Thanks, Allen.

9           Our next speaker is Richard Gragg with  
10 Florida A&M University.

11           MR. GRAGG: Good morning. I'm Richard  
12 Gragg. I'm a professor of environmental science and  
13 policy at Florida A&M University School of the  
14 Environment. My specific discipline is toxicology,  
15 and I would say I'm speaking from the perspective of  
16 my 25 years -- I think my retirement form says 25  
17 point 6. I'm trying to get to 30 -- of teaching  
18 research and public policy in looking at the impact of  
19 environmental stressors on human health. As I  
20 tell my students, who I just turned in their grades  
21 this semester, that they have to cite their sources.  
22 So, my first comments are based on an article by Dr.  
23 Cash and others called "Scale and Cross Scale  
24 Dynamics: Governance and Information in a Multi-Level  
25 World."

1           I'd like to be able to continue to advocate  
2   to my students that the EPA meets Dr. Cash's  
3   statements or research where EPA has been a leader in  
4   facilitating the task of governance and information  
5   through overcoming the challenges of ignorance,  
6   mismatch, and plurality by being a leader in promoting  
7   institutional interplay, co-management, and serving as  
8   a bridging organization for all of the stakeholders of  
9   concern.

10           Let's see if I can get to my comments now.  
11   So, I believe that regulatory reform should enhance  
12   the protection of human health and the environment  
13   through the continued application and innovation of  
14   science and policy, especially for vulnerable  
15   citizens, including children, people of color in low  
16   wealth populations, and farmworkers who are  
17   disproportionately exposed and cumulatively impacted  
18   by pesticides and other environmental, social, and  
19   economic stressors. Thank you.

20           MR. KEIGWIN: Our next speaker is Sharon  
21   Selvaggio with the Northwest Center for Alternatives  
22   to Pesticides.

23           Oh, I skipped Steven.

24           MR. COY: Did you do that on purpose?

25           MR. KEIGWIN: No, sorry, Steven Coy on

1       behalf of the American Honey Producers Association.

2               MR. COY:   Steven Coy.   I'm a commercial  
3       beekeeper.   I'm also a farmer, and I'm better looking  
4       than Allen.

5               Someone asked me just yesterday has progress  
6       been made.   My answer is no, not real progress.   Yes,  
7       awareness on both managed bees, as well as all  
8       pollinators, has increased.   Communication between all  
9       stakeholders now exists.   Label language has been modified.  
10      Pollinator protection plans have been implemented.  
11      Yet, last year's winter loss of managed bees was  
12      nearly 30 percent, with an annual loss of 44 percent.  
13      This clearly indicates the nation's managed bees are  
14      not healthy, and nothing significant has been done to  
15      reduce the impacts of pesticides on them.

16              The distinction between bees under contract  
17      and those not under contract is illogical.   If bees  
18      are truly to be protected from pesticide exposure,  
19      they must be protected from pesticides throughout the  
20      year, regardless of where they're located.   Contract  
21      or no contract, bees are not expendable.

22              The recommendation to eliminate that do not  
23      apply to blooming crops or weeds language from the  
24      environmental hazard section of the label is absurd.  
25      The label is the law, and prohibitory language such as

1     this must not be eliminated. Some state lead agencies  
2     claim this label language is unenforceable. Is it  
3     really or are they merely unwilling to enforce it?

4             Risk assessments should be conducted on  
5     formulated products, not simply active ingredients.  
6     In addition, risk assessments of IGRs, fungicides, in  
7     addition to that, the common tank mixes, including  
8     adjuvants, needs to be addressed/assessed for their  
9     ability to negatively impact brood development.

10            Every year, unnecessary damage to hives  
11     occurs due to lack of appropriate warning statements  
12     on the labels of these products. Rick Keigwin and OPP  
13     staff have indicated that this should start later this  
14     year on the common tank mixes, and I hope it does.

15            MP3s are good for establishing communication  
16     between beekeepers and pesticide applicators, but they  
17     are not the answer to solving the bee pesticide  
18     issues. Clear, enforceable label language which prohibits  
19     application of certain bee toxic compounds to blooming  
20     plants is the basis of effective pollinator  
21     protection.

22            The label language for neonics, which we  
23     challenged back in 2013, remains a very serious issue.  
24     The list of exemptions that allow applications to  
25     proceed from that label language, which are merely

1     loopholes that allow bee kills to occur legally. A 48-  
2     hour notification program should not be reason to  
3     allow legal applications of toxic products to blooming  
4     plants. It is impossible to move, cover, or otherwise  
5     protect all bee colonies within the area of pesticide  
6     applications to blooming plants.

7             The California model allows applications of  
8     bee toxic products 48 hours after notification as long  
9     as all label restrictions are followed. The 2013  
10    label language for neonics releases the applicator  
11    from liability as long as the notification is made.  
12    This is totally ridiculous.

13            All pesticide application recommendations  
14    are based on the threat of significant crop loss, so  
15    any application is allowed. Applications of long  
16    residual products made after sunset may save a few  
17    bees, but will likely kill many more bees in the  
18    ensuing days of the residual activity.

19            An EPA representative was publicly asked at  
20    a recent Crop Life of America conference if EPA  
21    honestly believes bees will be safer from pesticide  
22    exposure if this language were eliminated. After  
23    considerable hemming and hawing, the representative  
24    finally stated that he hopes so. He hopes so? Given  
25    all the bee health problems our industry continues to

1 face, we need real protection from pesticide exposure  
2 through better labeling restrictions, not less.

3 MR. KEIGWIN: Now Sharon Selvaggio with  
4 Northwest Center for Alternatives to Pesticides.

5 MS. SELVAGGIO: Thank you. Hello, my name  
6 is Sharon Selvaggio, and I'm honored to speak today on  
7 behalf of my organization Northwest Center for  
8 Alternatives to Pesticides located in Eugene, Oregon.

9 Founded in 1977, NCAP works to protect  
10 community and environmental health and inspire the use  
11 of ecologically sound solutions to reduce the use of  
12 pesticides. For the record, although the majority of  
13 my career has been spent in conservation and  
14 management on federal land, I did manage a farming  
15 program for three years. We have thousands of farmers  
16 that we actively work with at NCAP.

17 So, the EPA has offered this opportunity to  
18 the public today to provide input on regulatory  
19 reform. At this time, we recommend that no  
20 regulations be repealed, particularly as they relate  
21 to safety of pesticides in regards to human health and  
22 the environment.

23 We have four main comments related to the  
24 need to maintain such existing regulations. Pesticides  
25 are hazardous materials designed for the purpose of



1     killing or suppressing pests. The World Health  
2     Organization tells us that pesticides have caused  
3     millions of cases of human poisoning.

4             Additionally, many pesticides have been long  
5     acknowledged to be carcinogenic. The scientific  
6     evidence links others to neurodevelopmental and other  
7     serious conditions. EPA's regulations, starting from  
8     registration and extending through residue limits are  
9     designed to limit these risks.

10            FIFRA is already limited in its statutory  
11     reach by the requirement that pesticide registration  
12     decisions involve a cost benefit assessment, the  
13     narrow unreasonable adverse effect clause. This acts  
14     as a built-in check on so-called regulatory overreach  
15     that might result from a more absolute direction to  
16     protect human health and the environment.

17            Using the regulatory environment in the U.S.  
18     may have little effect for growers. Any grower  
19     exporting food is aware that the tolerance standards  
20     set by other countries are frequently more restrictive  
21     than those in the U.S. Regulatory reform is likely to  
22     create more difficulty for American growers to access  
23     export markets, not less.

24            And then, regulations do not exist in a  
25     vacuum but often have the effect of spurring

1 technological innovations. Just yesterday at the  
2 PPDC, we learned of the development of sterile insect  
3 release and genetically engineered mosquitoes to combat  
4 the Zika virus. These technologies and the ability to  
5 harness them in such a dramatically short amount of  
6 time likely would never have been possible without  
7 pesticide regulation on behalf of safety in the  
8 environment. These technologies, you know, have been  
9 in development for other pest problems for decades.  
10 So, the Zika virus effort was able to take advantage  
11 of technological advances that have occurred in the  
12 past.

13           On modification, we do have two comments.  
14 Far from acting as a damper on business activity, EPA  
15 has generally ignored pesticide impact to the most  
16 vulnerable species, those listed under the Endangered  
17 Species Act. To our knowledge, necessary procedures  
18 to assess pesticide impact to listed species, as  
19 recommended by the National Academy of Sciences, are  
20 not codified in any current regulation.

21           As a result, almost none of the registered  
22 active ingredients on the market today have been  
23 analyzed for the impacts on listed species. Of  
24 those that have, more than 20 active ingredients  
25 remain on the market, despite the fact that these

1 active ingredients have been determined to jeopardize  
2 the continued existence of dozens of species of  
3 Pacific salmon.

4 So, we recommend that registration  
5 regulations be strengthened to incorporate the  
6 concepts and procedures for listed species  
7 evaluations, as outlined in the 2013 NAS report during  
8 the registration and registration review processes.

9 Finally, no federal requirement exists for  
10 pesticide use reporting. This hampers society's  
11 ability to understand how actual use is related to  
12 empirical data on impact to human health and the  
13 environment. We think requiring such data and having  
14 it available would actually streamline difficult and  
15 controversial analyses such as consultation documents.  
16 So, we recommend that the EPA modify existing  
17 regulations to require mandatory pesticide use  
18 reporting. Thank you for the opportunity to speak.

19 MR. KEIGWIN: And the last member from the  
20 PPDC who is registered to speak this morning is Ray  
21 McAllister with Crop Life America.

22 MR. McALLISTER: My name is Ray McAllister.  
23 I'm the Senior Director of Regulatory Policy for Crop  
24 Life America. We're the national trade association  
25 that represents the manufacturers, formulators, and

1 distributors of crop protection products in the U.S.  
2 We will be submitting written comments for the docket  
3 but wanted to make a few brief remarks here.

4           We recognize this is one of multiple  
5 opportunities and forums to discuss and advance  
6 regulatory improvements, both grand and small.  
7 Agriculture as a whole depends on a predictable,  
8 science-based, and robust regulatory process to allow  
9 crop protection products to reach farmers in a timely  
10 fashion and to ensure that crops are protected, food  
11 is safe, and the environment is also protected.

12           We recognize the burden placed on American  
13 industry and agriculture by unnecessary, duplicative,  
14 or overly complicated regulations, no matter how well  
15 intentioned. We support efforts to streamline the  
16 regulatory process and to make certain that it is  
17 guided by common sense.

18           But we don't want to throw out the baby with  
19 the bath water. In the middle of regulatory reform,  
20 we do not want the basic, but hard, and important work  
21 done by OPP, to be lost or delayed.

22           To help support OPP's important work, CLA  
23 asks that the administration support reauthorization  
24 of PRIA, the private sector funded fee for service  
25 system that provides a portion of resources needed for

1       OPP to do its work in a timely fashion.

2               We also urge the Administration to budget  
3       funding to states to support pest control operations  
4       and to support technology, product development at  
5       agencies like EPA and USDA. Pest surveillance and  
6       pest control to deal with mosquitoes is as important as  
7       is vaccine development.

8               While we support OPP's mission, the Agency  
9       needs a reset in some areas to preserve risk-based  
10       regulation for pesticides based on sound science and a  
11       predictable regulatory process. Past weaknesses in  
12       EPA's risk assessment process have threatened the  
13       effectiveness and range of crop protection tools  
14       available to farmers and ranchers. Resetting the  
15       process in science and restoring transparency and  
16       predictability to the registration and review of  
17       pesticides can resolve many of these concerns.

18               We believe that USDA's role is essential.  
19       We are confident that regulator and meaningful  
20       involvement of USDA and its extensive expertise can  
21       help improve the process of regulating crop protection  
22       products that are so critical for American  
23       agriculture.

24               As we discussed yesterday, we can do better  
25       when it comes to proper implementation of the

1     Endangered Species Act. We look forward to continuing  
2     the hard work to find a path forward at the  
3     intersection of FIFRA and ESA. Thank you.

4             MR. KEIGWIN: Thanks, Ray.

5             We have a few minutes before the break. Let  
6     me just see if there are other members from the PPDC -  
7     - Robyn Gilden?

8             MS. GILDEN: Hi, I am with the University of  
9     -- Robyn Gilden with the University of Maryland School  
10    of Nursing and also the Alliance of Nurses for Healthy  
11    Environments. I'm not going to take my three minutes,  
12    but I just wanted to say thank you very much for  
13    having me on the PPDC for the past six years.

14            I also want to just encourage EPA to not  
15    take away regulations that protect human health. I'm  
16    a nurse. I care deeply about the health side of  
17    things. I care about the babies, and the elderly, and  
18    the pregnant moms, and the most vulnerable of our  
19    populations.

20            So, I want the public health protections to  
21    be the focus. I know that pesticides are important in  
22    their place, but I strongly support the IPM model  
23    where you eliminate the pests structurally before you  
24    get down to the chemicals. Thank you.

25            MR. KEIGWIN: Are there any other PPDC

1 members? Andy Whittington?

2 MR. WHITTINGTON: Thank you. Andy  
3 Whittington with the Mississippi Farm Bureau  
4 Federation on behalf of American Farm Bureau  
5 Federation.

6 I do want to support the comments submitted  
7 by USDA this morning. We are in concert with most of  
8 those comments, especially an extension of the  
9 compliance date with the WPS provisions. It's not  
10 necessarily about the content of the WPS provisions,  
11 but it is making sure that we have a timely manner to  
12 get all of the farmers, and handlers, and workers  
13 properly trained to be in compliance with those  
14 regulations.

15 There's plenty of evidence from the speakers  
16 this morning that EPA has an incredibly tough job to  
17 do balancing the need of the farmers and the  
18 consumers, as well as the environmental protections  
19 that are required. So, we do appreciate that effort,  
20 and we will be submitting comments to the docket  
21 related to this issue. Thank you.

22 MR. KEIGWIN: Any other PPDC members? Oh,  
23 Valentin, Valentin Sanchez with the Oregon Law Center.

24 MR. SANCHEZ: Good morning, everyone. My  
25 name is Valentin Sanchez. I currently work with the

1 Oregon Law Center as a community educator. Prior to  
2 that, I was a farmworker for several years. My  
3 parents are currently working as farmworkers in Santa  
4 Maria, California. I'm very excited that we, you  
5 know, do special accommodations to listen to people --  
6 I wish we could do special accommodations to listen to  
7 the stories of farmworkers.

8 My native language is not Spanish; it's  
9 Mixteco. Pretty soon, we're going to start  
10 reaching out to farmworkers in the state of Oregon.  
11 In the state of Oregon, there are over 160,000  
12 farmworkers and more if we add the family members as  
13 well. So, I've been speaking with farmworkers for the  
14 last 14, 15 years visiting labor camps, conducting  
15 outreach to parents, just making sure that the  
16 community knows about, you know, the few laws to  
17 protect them.

18 So, I want to speak to the importance of  
19 WPS. I've been speaking with farmworkers, and about  
20 half of them are receiving training about how they can  
21 protect themselves and protect their family members.  
22 Even those who do receive training are receiving  
23 inadequate training because the materials that are  
24 being used were developed in the 1990s. So, there's a  
25 need for better information. There's a need for more



1 resources to make sure that farmworkers know how they  
2 can protect themselves.

3 I also want to quickly mention the  
4 importance of having the designated representative.  
5 As I've said, I've spoken with farmworkers who are  
6 afraid of speaking with their employers because  
7 they're afraid of being retaliated against, they're  
8 afraid of losing their jobs. So, oftentimes they  
9 don't speak up for themselves. They need to rely on  
10 someone else to obtain information about which  
11 pesticide they were exposed to.

12 So, this is very important, especially for  
13 clinicians, to be able to treat the patient who has  
14 been exposed to pesticides. They need to know the  
15 name of the chemical that they were exposed to.

16 So, I want EPA to continue to, you know,  
17 implement, have worker protection standards. Very  
18 important. There's a huge need in the farmworker  
19 community. So, I want to encourage you to continue to  
20 do that. Thank you.

21 MR. KEIGWIN: Let me just see if there's --  
22 we probably have time for one more. Dawn Gouge?

23 MS. GOUGE: Thank you. Dawn Gouge, urban  
24 entomologist at the University of Arizona. I would  
25 just ask EPA to not delay the implementation of worker

1 protection standards, not for a minute. There's two  
2 things that drive innovation: regulation and  
3 disasters. Let's go the regulation way rather than  
4 further disaster.

5 I'm a strong advocate for integrated pest  
6 management and integrated vector management. So, I  
7 just wanted to throw that term out there so that  
8 everybody goes away and Googles integrated vector  
9 management. Thank you.

10 MR. KEIGWIN: Okay, so we're at about 10:00  
11 Eastern Time. We're going to take a 15-minute break.  
12 And then, when we return, we'll open it up for public  
13 comments. We'll start with people who are here in the  
14 room in Virginia and then we'll turn things over to  
15 people who are participating via telephone. Thank  
16 you.

17 (A brief recess was taken.)

18 MR. KEIGWIN: Okay, everybody, if we could  
19 take our seats, and we'll start the public comment  
20 session. So, we're going to move on to the public  
21 comment session now. We will start with people who  
22 registered in advance and are here in the room here in  
23 Crystal City. We have posted up on the screen here  
24 the order in which people registered to speak.

25 So that I don't butcher names, if you could

1 just come up to the mic that's here in the center of  
2 the room, introduce yourself and your affiliation.  
3 And as with the session earlier this morning, there's  
4 enough time for about three minutes of remarks. Dea  
5 will hold up her one minute warning sign.

6 So, I believe the first speaker registered  
7 is Julie Spagnoli, and we can go from there.

8 MS. SPAGNOLI: Julie Spagnoli, JM Specialty  
9 Consulting. I'm an independent consultant, but I've  
10 been in this industry for about 33 years. So, I've  
11 been involved with OPP for a long time.

12 I've recently also become a farmer in the  
13 last four years, so I've gotten out and learned  
14 firsthand how difficult farming can be and some of the  
15 challenges that you face when you actually go out  
16 there and do it.

17 But to speak specifically to this topic, I  
18 just wanted to touch on a few things. I won't go into  
19 a lot of details. We know that the Agency is facing  
20 limited resources in a lot of areas. We've seen it in  
21 particular in the registration area.

22 So, one of the suggestions is to look at  
23 ways that we can reduce any unnecessary paperwork  
24 burdens for both the industry and the Agency,  
25 paperwork that's just not really used for any

1 particular purpose. This would include things like  
2 final printed labeling, which because of the new  
3 process that we have for getting label approvals, the  
4 label is approved as a complete label. The final  
5 printed label is made. There may be multiple  
6 packages. It's really not serving a useful purpose  
7 for the Registration Division. It is, obviously, a  
8 compliance and enforcement issue, but that's done out  
9 in the field.

10 The other one, and it was touched on earlier  
11 from the antimicrobial side, but also from the  
12 registration side, is use of notification. That can  
13 be a way to greatly streamline process for both the  
14 Agency and registrants. We'd like to see that process  
15 kind of go back to where it used to be where it really  
16 was a notification. That way, like I said, it's less  
17 paperwork for the Agency for processing and less work  
18 for the registrants.

19 The last one is the use of what we want to  
20 call a commonly used or commodity inert. These are  
21 inerts that are commonly used materials such as corn  
22 cob, peanut holes, food items like dried milk or  
23 peanut butter. Right now the rules require that the  
24 registrant must identify every potential supplier of  
25 those inerts, and it just creates a paperwork burden

1     where they have to file a new confidential statement of formula,  
2     every time they add a supplier. For materials like that, it  
3     just becomes a paperwork exercise and really doesn't provide any  
4     additional protection.

5             There will be probably more details on some  
6     of these things, but those are just some of the things  
7     we think can streamline the processes. Thank you.

8             MR. KEIGWIN: The next speaker is Steven  
9     McFadden.

10            (No response.)

11            MR. KEIGWIN: Okay, the next person we have  
12     registered is Kerry Richards.

13            MS. RICHARDS: Good morning. I'd like to  
14     thank you for the opportunity to speak. I spent the  
15     last 27 years of my career at the pesticide safety  
16     education program at Penn State University. For seven  
17     years, I was director of that program.

18            Currently, I'm working with the University  
19     of Delaware to revitalize their pesticide safety  
20     education program. I'm working 40 percent of the time  
21     with the new initiatives. That is the National  
22     Pesticide Safety Education Center. That 40 percent  
23     time means that now instead of working 180 hours, like  
24     most of my colleagues do, I only work about 40 hours a

1 week.

2           So, I'm not speaking on behalf of any of  
3 those organizations, but I wanted to give you a  
4 perspective of my years and perspective of over 30 years  
5 as a pesticide safety educator and someone who grew up  
6 on a research farm who did research on chemicals and  
7 pesticides that came onto the market.

8           Before I do that, I did have one of my AAPSE  
9 membership ask me to just kind of relay the  
10 concern about EPA's mandate or requirement to help  
11 support pesticide safety education programs through  
12 funding, through state programs. It is in FIFRA law  
13 that the EPA -- it's stated that the EPA is to use the  
14 cooperative extension services to provide training.  
15 The extension service is overseen by USDA NIFA and, as  
16 such, is part of the land grant institution.

17           With EPA's mandate to ensure that state  
18 plans provide state funding to pesticide safety  
19 education programs, he indicates that he feels that it  
20 can be perceived as any state at any time desires a  
21 certified applicator, the governor shall decide which  
22 program and the EPA administrator shall approve those  
23 state programs. I mean, if it requires that approval,  
24 that support for pesticide safety education programs  
25 financially should be included in that approval of the

1 state plan.

2 What I wanted to bring to -- Liza spoke much  
3 of the comments I was going to make. We're going to  
4 submit them publicly. So, in the interest of time, I  
5 would just echo what Liza said and ask that the EPA do  
6 their diligence in providing education by helping and  
7 continuing to support pesticide safety education that  
8 serve in all 50 states.

9 I've been the classic example of when there  
10 is support from those Departments of Agriculture in  
11 Pennsylvania. They were hugely supportive of our  
12 program, and we were able to serve not only the  
13 certified applicators in Pennsylvania but the  
14 consumers and the public as well.

15 Over the last three years, I've been working  
16 with Delaware, who received no support from their  
17 Department of Agriculture. Like most of my  
18 colleagues, many states do the same thing. It's like  
19 being McGyver where you just pull all the pieces apart  
20 and somehow we accomplish the purposes and educate the  
21 stakeholders, the growers, the workers, and everyone  
22 that is out there that can potentially be affected by  
23 the misuse or the concerns of pesticide exposures.

24 So, I would urge EPA to continue that  
25 support and increase it whenever possible, especially

1 with the new National Pesticide Safety Education  
2 Center. The mission is to gather all these resources,  
3 not just from pesticide safety education programs but  
4 all the resources out there, so there's one consistent  
5 repository so everyone can utilize their educational  
6 materials to the most effective use and most efficient  
7 use.

8 MR. KEIGWIN: Thank you.

9 Jennifer Sass from NRDC.

10 MS. SASS: Thanks very much. Thank you for  
11 the opportunity to provide comments to support the  
12 EPA's pesticide office and the important work that you  
13 guys do.

14 NRDC, the Natural Resources Defense Council,  
15 is speaking on behalf of our two million members and  
16 online supporters. NRDC objects to the false premise  
17 of the executive order that public safeguards are or  
18 would hold back the nation.

19 In reality, the safeguards that the Office  
20 of Pesticide Programs must provide to the public are  
21 vital to the health and safety of all, particularly  
22 children and future generations. They're good for  
23 business and the U.S. economy. I have citations to a  
24 number of letters and articles from the ASBA, the  
25 American Sustainable Business Association, testifying



1 to that.

2 One important critical example of the health  
3 protective safeguards of the Office of Pesticides has  
4 been the Food Quality Protection Act, FQPA. It was a  
5 bipartisan law that passed Congress unanimously in  
6 1996 and the first environmental law that required  
7 pesticide regulations to include specific protections  
8 for the health of infants and children.

9 As a result of FQPA implemented by the  
10 pesticide office, the nation's use of pesticides has  
11 moved away from some of the most dangerous ones,  
12 particularly the organophosphates, or OP insecticides.  
13 EPA actions to protect children from harmful  
14 pesticides is good for health and good for business.

15 A 2015 European Union study cited costs  
16 associated with lost IQ points and intellectual  
17 disabilities arising from only two categories of  
18 chemicals, the PBDEs, polybrominated diphenyl ethers,  
19 which are flame retardants, and organophosphate  
20 pesticides, are estimated at 155 billion euros, about  
21 \$170 billion US annually for one member. There are  
22 citations for all of that that are included.

23 For one member of the OP pesticides,  
24 chlorpyrifos, scientists have shown that it interferes  
25 with brain development resulting in poor working

1 memory and reduced IQ and developmentally exposed  
2 children. For these reasons, all home uses of  
3 chlorpyrifos were cancelled in 2001, but the  
4 negotiated requirement for that cancellation was that  
5 although there was a reduction of over six million pounds  
6 annually used in people's homes, the agriculture uses  
7 were able to continue.

8 EPA's protective actions on chlorpyrifos in  
9 the residential cancellations resulted in a 66 percent  
10 reduction in poisonings since that, demonstrating the  
11 importance of regulatory safeguards for keeping our  
12 loved ones safe. I have references to that from  
13 presentations by EPA to the PPDC in November of 2006.

14 Unfortunately, chlorpyrifos, while no longer  
15 allowed in homes, is still allowed in agriculture at  
16 somewhere between 5 and 10 million pounds a year on  
17 many crops, including crops that children regularly  
18 eat, as well as being responsible for a number of  
19 worker poisonings and drifts to suburban and  
20 residential homes.

21 Federal experts also reported recently that  
22 chlorpyrifos and other organophosphate pesticides  
23 still used on crops are harmful to almost 1,800  
24 critically threatened or endangered species, making it  
25 a threat to wildlife and ecosystems as well.

1           Over 60 scientists and medical professionals  
2     wrote in 2016 to support EPA in their proposal to  
3     cancel all food tolerances. Under the Obama  
4     Administration, EPA developed a 2015 proposal, again  
5     confirming it in 2016 to do this.

6           Unfortunately, the White House and Dow  
7     Chemical, which donated \$1 million to President  
8     Trump, and whose CEO is the White House pick for  
9     heading up the American Manufacturing Council, appears  
10    to have dodged the cancellation. Instead of enforcing  
11    legally mandated safeguards, Pruitt Pollutes  
12    is allowing EPA to let this continue to harm children.  
13    Thank you.

14           MR. KEIGWIN: Next speaker is Peter Jenkins  
15    with the Center for Food Safety.

16           MR. JENKINS: Thank you, Rick, and members  
17    of the panel. I'm an attorney and policy analyst for  
18    the Center for Food Safety, a nonprofit group  
19    headquartered in DC but with offices in San Francisco,  
20    Portland, Oregon, Honolulu, and 830,000 members.

21           First, I want to address President Trump's  
22    Executive Order 13771, which was in the materials.  
23    It's sort of part of this deregulatory package but  
24    hasn't been talked about yet. That's the one that  
25    proposes elimination of two existing regulations for

1 each new regulation adopted.

2 I think there's been no support for that  
3 from any speaker. I don't think you're going to find  
4 any support for that from anyone familiar with this  
5 pesticide regulatory world. There's no place for it  
6 in the FIFRA pesticide context. For example, the  
7 tolerances for pesticides on foods are adopted by  
8 regulation. It's absurd to suggest that you should  
9 eliminate two tolerances for each new tolerance  
10 adopted.

11 So, we hope that your agency recognizes that  
12 the two for one idea is inherently arbitrary and  
13 capricious, would violate underlying statutory  
14 standards and is going to lead to unnecessary  
15 litigation. So, convince the administrator to  
16 convince OMB that the two for one really has no place  
17 in this world.

18 Now, with respect to the President's  
19 Executive Order 1377, which is kind of the focus here  
20 on regulatory costs, I guess I would respectfully  
21 disagree with some other speakers that the questions  
22 under that public announcement that EPA put out were  
23 not good questions, because there are some good  
24 questions there. For example, which existing  
25 regulations are obsolete, which existing regulations

1 are not transparent, which existing regulations are in  
2 need of modification.

3 There are several. We will submit written  
4 testimony to that effect about several of them, but I  
5 want to just focus on two of high priority. The first  
6 is 40 CFR 152.25A, otherwise known as the treated  
7 article exemptions, adopted in 1988.

8 1988 was long before this notion of using  
9 systemic seed coatings as pesticides to get absorbed  
10 into the plant and then make the plant itself  
11 pesticide before that was realized. Yet, the Agency  
12 is using that 1988 treated article exemption to exempt  
13 the most prevalent widespread use of insecticides in  
14 the country, which is the seed coatings, the  
15 neonicotinoid seed coatings, clothianidin,  
16 thiamethoxam, and imidacloprid especially. That's  
17 causing extreme harm and burden on the environment, on  
18 water quality, and I'm going to mention in particular  
19 with respect to beekeepers.

20 Last week, the three major beekeeping  
21 organizations in the country, along with several  
22 environmental groups, the American Bird Conservancy,  
23 Center for Food Safety, individual beekeepers and  
24 farmers all submitted a petition to you to revise your  
25 interpretation of that old out-of-date obsolete

1 regulation to bring it into the current reality, which  
2 is, you've exempted the most widespread use of  
3 insecticide in the country from actual enforceable  
4 labels and actual safety standards that the farmers  
5 have to comply with.

6 As a result, beekeepers have no recourse  
7 when their bees get killed by the dust. There's no  
8 enforcement against the harms that are being caused  
9 from these coated seeds going into the waters, killing  
10 birds, killing bees, you name it. American Honey  
11 Producers Association, American Beekeeping Federation,  
12 Pollinator Stewardship Council have all endorsed it.

13 When the three major national beekeeping  
14 organizations are telling you you need to change your  
15 regulation, you should take it seriously if you want  
16 to get serious about protecting bees, which is an  
17 important big ag interest, very important to  
18 agriculture. Pollination is suffering, yet your  
19 regulatory problem has created this loophole. So,  
20 reform that one, please.

21 MR. KEIGWIN: So, I think in the interest of  
22 time, I think we need to go on to the next speaker.  
23 If there's time remaining, you could come back up.  
24 But we do have a number of other speakers registered.

25 MR. JENKINS: Thank you, will do.

1 MR. KEIGWIN: Daniel.

2 MR. RAICHEL: Good morning, my name is Dan  
3 Raichel. I do eat food, and I have a  
4 family that I want to protect, which is probably why  
5 I'm an attorney with the Natural Resources Defense  
6 Council, which for over 45 years has fought to protect  
7 people and the environment from the harms of toxic  
8 chemicals.

9 I speak today to remind the Agency, as it  
10 appears poised on carrying back critical protections  
11 for clean air, clean water, and healthy ecosystems,  
12 that it is not at liberty to shirk its  
13 responsibilities under our nation's bedrock  
14 environmental laws by eliminating regulations. It  
15 needs to comply with those laws.

16 Specifically, EPA must not attempt to cut  
17 corners in its mandatory review of registered  
18 pesticides, including assessment of their known or  
19 likely harms to our nation's pollinators and  
20 endangered species. Some of those harms are already  
21 apparent. For over 10 years, we've seen bee  
22 populations succumb to massive losses, concurrently  
23 with the growth and widespread use of a new class of  
24 pesticides, neonicotinoids or neonics.

25 Indeed, just this March, the rusty patched

1 bumblebee, once common in 28 states, became the first  
2 bee in the continental U.S. to be placed on the  
3 endangered species list. The listing decision  
4 identifies the use of neonics as a contributing factor  
5 in the bee's close to 90 percent decline in the last  
6 20 years.

7           Equally, or perhaps more important in the  
8 well known harms however, are the ones that we are  
9 just now learning about. In January, EPA put out  
10 biological evaluations for three pesticides,  
11 chlorpyrifos, diazinon, and Malathion, concluding that  
12 collectively, their use is likely to adversely affect  
13 almost 1,800 protected species. These evaluations  
14 represent only a small fraction of the outstanding  
15 endangered species evaluations EPA now needs to  
16 perform.

17           Performing those evaluations, along with the  
18 required registration reviews, is important work.  
19 Significantly, it is also work EPA is required to do  
20 by law. The Agency must ensure that any action it  
21 carries out is not likely to jeopardize a federally  
22 protected species and that the pesticides it registers  
23 do not cause unreasonable adverse effects on people or  
24 the environment.

25           That work is fundamental to the Agency's



1 purpose. It ensures that our ecosystems aren't  
2 hallowed out by careless disregard, that Americans  
3 aren't needlessly exposed to toxic pesticides, and  
4 that in the case of pollinators, we do not heedlessly  
5 destroy a group of species that are critical to  
6 producing 70 percent of the major crops we consume.

7 Now, over the years, EPA has developed rules  
8 designed to assure that the Agency complies with the  
9 letter of the law. Those rules cannot now be  
10 eliminated only to satisfy an arbitrary rulemaking  
11 principle -- and that's just what Peter just talked  
12 about -- particularly when they are essential to  
13 protecting people and natural resources like  
14 pollinator populations that we all depend on.

15 Accordingly, as EPA moves forward with  
16 implementation of the president's executive order, we  
17 caution the Agency to be mindful of its mandatory  
18 statutory responsibilities and that we will be  
19 watching this process very carefully. Thank you.

20 MR. KEIGWIN: Our next speaker is Tiffany  
21 Finck-Haynes.

22 MS. FINCK-HAYNES: Thank you. I'm here  
23 representing Friends of the Earth and our over one  
24 million members and supporters nationwide. Friends of  
25 the Earth is a national environmental organization

1       that is working to defend the environment and champion  
2       a healthy and just world.

3               We're part of a federation of groups  
4       internationally working in 76 countries on today's  
5       most urgent environmental and social issues.  
6       Discussing what existing pesticide regulations should  
7       be fleshed is sacrificing public health on the altar  
8       of corporate profits and will destroy America, not  
9       make it great.

10              Pesticide regulations have a number of  
11       benefits, including protecting our environment, our  
12       critical habitat, wildlife, water, soil, and public  
13       health. Many of the pesticides EPA is currently  
14       reviewing are highly toxic and contribute to human  
15       diseases such as cancer and liver disease.

16              Other countries have restricted or banned  
17       these pesticides, such as glyphosate,  
18       neonicotinoids, atrazine, and pyrethroids.  
19       Regulations on these chemicals should be strengthened  
20       to follow in the footsteps of what other  
21       countries have done. We must take these chemicals off  
22       the market to safeguard public health and the  
23       environment.

24              We urge EPA to not put millions of lives at  
25       risk so that polluters can further profit from

1     destruction of our environment. Pesticide regulation  
2     should be grounded in science and the law so that our  
3     soil, water, wildlife, and public health can keep us  
4     healthy and thriving.

5             We believe this conversation is dangerous  
6     and based on corporate greed and environmental  
7     pollution. We call on EPA to uphold its mission and  
8     protect public health and our environment by  
9     strengthening existing laws and regulations. Thank  
10    you.

11            MR. KEIGWIN: So, I believe our next speaker  
12    is going to be Brett Hartel. Jim Tozzi, who is up on the  
13    board, had to leave early.

14            MR. HARTEL: This is Brett Hartel at the  
15    Center for Biological Diversity. I'll do my best to  
16    keep this to three minutes, but I don't have a million  
17    dollars like Dow Chemical to give to President Trump.  
18    So, if I go over, I apologize.

19            The premise of this ridiculous sham hearing  
20    that the pesticide industry is somehow overburdened by  
21    reasonable regulations designed to protect the health  
22    of people, wildlife, and the environment we share is  
23    fatally flawed. Donald Trump and Scott Pruitt's  
24    transparent attempts to enrich themselves and their

1 special interest masters quite literally puts lives at  
2 risk. It puts our environment at grave risk, and it  
3 moves dozens of endangered species closer to  
4 extinction.

5 To suggest that common sense measures to  
6 protect us all from toxic chemicals should be repealed  
7 is unconscionable and will not be tolerated by the  
8 American people. The notion that the pesticide  
9 industry, which includes some of the richest  
10 corporations in the world, with billions in profits  
11 last year, can't handle the so-called burdens of  
12 regulations is laughably absurd.

13 The pesticide industry has effectively  
14 written most of the regulations that govern the  
15 pesticide approval process. As a result, thousands of  
16 miles of streams and rivers are impaired by the EPA's  
17 own estimates by pesticide pollution. The last time  
18 the EPA had the courage to cancel a pesticide due to  
19 the imminent hazard provision of FIFRA was more than  
20 30 years ago.

21 The so-called ecological risk assessment  
22 process now in place is not much more than a rubber  
23 stamp to approve pesticides that conclude that  
24 everything is fine, when it isn't. And yet, the  
25 pesticide industry cries that the sky is falling when

1 actual scientists at the US Fish and Wildlife Service  
2 and the National Marine Fishery Service conclude that  
3 an insecticide, like chlorpyrifos, might actually kill  
4 endangered insects like butterflies.

5 But here are the actual facts. There are  
6 270 different recovery plans for endangered species  
7 that have concluded that pesticides are a key threat  
8 to their survival and recovery. In the last few  
9 years, species like the Dakota skipper and the rusty  
10 patch bumblebee have needed protection under the  
11 Endangered Species Act because of status quo use of  
12 pesticides.

13 The facts are irrefutable. The EPA  
14 desperately needs to improve and strengthen its  
15 existing regulations so that ecological risk  
16 assessment process complies with the law, and it  
17 protects people and endangered species. Instead of  
18 protecting industry, EPA should do what is needed to  
19 be done to protect people from the more than one  
20 billion pounds of pesticides that are applied across  
21 the United States every year.

22 I'll note, and it's simply a matter of law,  
23 any time this Agency takes a discretionary action to  
24 repeal any regulation or to weaken a regulation that  
25 harms an endangered species, we will fight you every

1 step of the way.

2 MR. KEIGWIN: Our next speaker is Stephanie  
3 Kurose. I apologize if I pronounced that  
4 incorrectly.

5 MS. KUROSE: No, that's right. Hi, my name  
6 is Stephanie Kurose, and I am with the Center for  
7 Biological Diversity. My parents are beekeepers, so  
8 this issue is near and dear to my heart. But today  
9 I'm not going to talk about bees; I'm going to talk  
10 about the monarch.

11 The monarch is a beautiful animal, and it's  
12 an incidental pollinator. There used to be so many of  
13 them that the sound of their wings was described as a  
14 rippling stream for a summer rain. There are early  
15 descriptions of tree branches breaking from the weight  
16 of so many butterflies. Every winter, they undertake  
17 a legendary 2,000 mile journey from Canada to their  
18 over wintering sites in Mexico. They use the very  
19 same trees every year when they migrate, which is  
20 pretty amazing because they aren't the same  
21 butterflies that were there the year before.

22 Now, thanks to glyphosate and the widespread  
23 use of pesticides and herbicides, monarchs are now  
24 plummeting towards extinction. The monarch population  
25 has declined over 80 percent in the last 20 years.

1 The 2017 overwintering count released in February  
2 found that butterfly numbers fell by nearly one third  
3 from last year's count. Scientists estimate that the  
4 monarch has lost more than 165 million acres of  
5 habitat, an area about the size of Texas, in the last  
6 20 years. They have also lost nearly a third of their  
7 summer breeding ground.

8 Last year, a study by the U.S. Geological  
9 Survey concluded that the monarch now faces extinction  
10 within 20 years. Monarchs only eat one thing, and  
11 it's milkweed. The animals used to rely on milkweed  
12 in corn and soybean fields in the Midwest until  
13 glyphosate started being widely used, which kills  
14 milkweed.

15 Glyphosate is now used on over 90 percent of  
16 all corn and soy and has removed nearly all the  
17 milkweed. So, basically, you have one type of  
18 herbicide that has virtually wiped out an entire  
19 species. California recently announced that it would  
20 list glyphosate as a human carcinogen under its  
21 Proposition 65. Yet, pesticide companies want a  
22 swift re-registration of the ingredient.

23 Honestly, I'm in disbelief that the EPA  
24 would consider anything less than issuing more  
25 stringent regulations over the use of toxic

1 pesticides. Instead, we're here at the behest of  
2 Scott Pruitt who hates the mission of environmental  
3 protection to gut regulations. The idea that EPA  
4 would hesitate to regulate chemicals that can wipe out  
5 pollinators critical to our ecological health and food  
6 security is beyond ridiculous.

7 Now is not the time to be complacent. We  
8 will have tragic consequences if you guys don't act to  
9 safeguard humans and wildlife from toxic chemicals.  
10 Thank you.

11 MR. KEIGWIN: Our next speaker is Howard  
12 Crystal.

13 MR. CRYSTAL: Good morning, my name is  
14 Howard Crystal. I'm an attorney in the Climate Law  
15 Institute at the Center for Biological Diversity.  
16 Because this meeting is being conducted to carry out  
17 the regulatory reform executive order, I want to begin  
18 by reiterating that while the executive order directs  
19 agencies to remove "unnecessary regulations," it also  
20 makes clear that it must be done "consistent with  
21 applicable law."

22 Therefore, while the executive order speaks  
23 to reforming regulations which may be outdated or  
24 ineffective, it does not and cannot give EPA the power  
25 to alter Congress' mandate that you prevent



1     unreasonable adverse effects on the environment from  
2     pesticides.

3             Regulating pesticides, like any other  
4     regulation, imposes some burden. It would obviously  
5     be more profitable to simply sell a poison than to get  
6     government approvals, create proper labeling, and  
7     ensure appropriate usage. But congress made the  
8     judgment in FIFRA that just a minor burden pales in  
9     comparison to the public benefit of protecting humans  
10    and the environment from harmful chemicals. Neither  
11    the executive order nor this agency has the  
12    constitutional power to change either that judgment or  
13    the EPA's mandate under the statute.

14            To follow that congressional mandate, it is  
15    absolutely clear that rather than remove regulations,  
16    EPA has enormous work to do to protect the environment  
17    from the ongoing environmental harm caused by  
18    pesticides. For example, it is well recognized that  
19    in addition to human harm, pesticides are responsible  
20    for putting other species in peril of extinction.  
21    Salmon, frogs, and salamanders are just a few of the  
22    species especially sensitive to pesticides, and  
23    further regulations of pesticides is essential to  
24    protect and recover these species.

25            It's also essential to consider the

1 relationship between climate change and pesticide use.  
2 By reversing progress made to combat climate change,  
3 this administration is exacerbating changes in weather  
4 patterns and other factors that will undoubtedly pose  
5 increasing challenges to farmers in years to come.

6           Allowing increased reliance on pesticides to  
7 mitigate those challenges may well become tempting,  
8 but it cannot be more clear that the most effective  
9 and cheapest way to address these problems is to take  
10 the steps necessary to minimize climate change rather  
11 than trying to protect our food supply from its impact  
12 by further poisoning the environment with toxic  
13 pesticides. Thank you.

14           MR. KEIGWIN: Our next speaker is Bill  
15 Jordan.

16           MR. JORDAN: Thank you for the opportunity  
17 to speak to you. My name is Bill Jordan, and I used  
18 to work at EPA. I'm now an independent consultant  
19 working with law firms, corporations, environmental  
20 advocacy organizations, and the like.

21           I want to start off by noting that the  
22 comments so far have just suggested a lot more work  
23 than I think is possible for EPA to do. So, you all  
24 are going to have to make some choices about which of  
25 the proposals you pursue. I'd like to offer a

1 suggestion about a way to think about that.

2 I think you ought to try to find regulatory  
3 relief that reduces burdens and at the same time  
4 provides environmental protection or improves human  
5 health protection.

6 The second category of suggestions I think  
7 you should look at are those that improve efficiency  
8 which makes it possible for EPA to move regulatory  
9 decisions through more efficiently, more  
10 transparently, that provides support to the public so  
11 they can be effectively involved.

12 Then, the third category are the ones that  
13 are really tough choices where you're trading off  
14 reducing some regulatory burdens, but those regulatory  
15 burdens may also be ones that involve real  
16 protections. I think the suggestions about worker  
17 protection standards and certification training fall  
18 into that category.

19 I have one suggestion that nobody has  
20 mentioned that falls, I think, into the first  
21 category. That's how EPA policies affect the handling  
22 of damaged pesticide containers. Large lawn and  
23 garden stores like Home Depot or Walmart or others  
24 occasionally find that the bags of pesticides and  
25 fertilizers are damaged during transportation and

1     handling.  EPA says that those containers have to be  
2     diverted to the hazardous waste stream.

3             It seems to me that if there were another  
4     alternative, which EPA policies could promote, of  
5     repackaging and reconditioning those products safely,  
6     that it would both save money for industry and reduce  
7     the amount of pesticides that goes into the  
8     environment with no pesticidal benefit.

9             I have a number of suggestions that relate  
10    to clarifying the jurisdiction between EPA and other  
11    agencies that I think could fall into the second tier  
12    of changes, changes that would address, for example,  
13    places where jurisdictions are either overlapping or  
14    unclear or maybe both.

15            Pesticides and new animal drugs, for  
16    example, something that's added to an aquarium for  
17    protecting the fish from parasites, FDA's new animal  
18    drug or EPA's or what.  I think you could look  
19    seriously at pesticides and medical devices.  Most  
20    disinfectants are considered medical devices as well  
21    as pesticides.

22            There are several others I can go through at  
23    a later point.  Thank you.

24            MR. KEIGWIN:  Okay, that concludes those who  
25    had registered in advance.  We're now going to go to

1 the people who registered in advance on the phone.  
2 And then, time permitting, we'll come back to here in  
3 the room. So, at this point, I'm going to turn the  
4 moderator duties over to my colleague, Claire  
5 Gesalman.

6 MS. GESALMAN: Thank you very much. I  
7 would ask as I call a person's name who has registered  
8 to speak on the phone, that you press pound 6 to  
9 unmute your line. You will hear the operator say  
10 unmuted. At that point, please give your name and, if  
11 you have an affiliation, you may give that.

12 We will say thank you or something along  
13 that line, at which point you know we're hearing you  
14 and you can go ahead and speak. Each person has three  
15 minutes. Since I can't hold up a card to the folks on  
16 the phone, if you can keep an eye on your clock, and  
17 I'll basically tell you when your time is up. Then,  
18 when the time is up for your three minutes, please  
19 press star 6 to remute yourself.

20 The first person on our list, and I  
21 apologize in advance if I mispronounce anyone's name,  
22 is Telisport Putsavage. Please press pound  
23 6 to unmute.

24 MR. PUSAVAGE: Good morning, I just unmuted.  
25 This is Telisport Putsavage.

1 MS. GESALMAN: Great, thank you. Go  
2 ahead.

3 MR. PUSAVAGE: Thank you. Thank you for the  
4 opportunity to address pesticide regulatory reform  
5 issues. By way of brief background, I'm an attorney  
6 with 35 years of FIFRA experience. I counseled the  
7 pest management program of the New York State  
8 Department of Environmental Conservation for 15 years,  
9 and I've had a FIFRA-focused private practice for 20  
10 years. I have also owned a farm.

11 The Agency is undertaking this examination  
12 of regulatory reform at a time when it is facing great  
13 stress, both budgetary and programmatic. As an  
14 example of already existing stress, I would note that  
15 while industry is fortunate to have PRIA and its  
16 deadlines, the resulting impact on non-PRIA actions  
17 have made the term fast track amendment an oxymoron.

18 In light of this stress, my suggestions  
19 focus not on rules to change but on urging the Agency  
20 to focus its efforts and resources in order to  
21 preserve the primary mission of the program. OPP  
22 should adhere to FIFRA and the rules as currently  
23 promulgated rather than stretching Agency and  
24 regulated party resources in efforts that are perhaps  
25 well-intentioned but ignore existing law and

1 regulation.

2 A most graphic recent example of this  
3 Overreach is the December 1, 2016, memorandum from the  
4 directors of the Registration and Antimicrobial  
5 Divisions, which allegedly clarifies requirements for  
6 the location of the first aid statement on labels of  
7 toxicity category two and three products. Not content  
8 with and notwithstanding the express authority of 40  
9 CFR 156.68(d), which states that such statements may  
10 appear "on any panel of a product," this memorandum  
11 purports for the first time under FIFRA to define the  
12 term panel in relation to a label.

13 In addition, the memorandum renounces the  
14 past agency approach to this issue, declaring that the  
15 new definition of panel has been in effect all along  
16 and intimates that the registrants face potential  
17 enforcement action against labels approved by the  
18 Agency.

19 Another example was a demand by a product  
20 reviewer expressly stating concern over childhood  
21 consumption of apples, that apples should be removed  
22 from an insecticide label. This demand expressly  
23 conflicted with the re-registration eligibility  
24 document, which determined that continued use of the  
25 ingredient on apples posed no unacceptable risk. That

1 position resulted in needless waste of time required  
2 to obtain reversal from highest level staff.

3 Another example is an effort by a region to  
4 prosecute a registrant for allegedly unlawful conduct  
5 over a 15-year period by a distributor registrant  
6 despite the fact that the Agency acknowledges that the  
7 primary registrant canceled the distributor  
8 registration (inaudible) earlier.

9 Well, the rules clearly provide that a  
10 primary registrant is liable for the conduct of a  
11 distributor registrant. Agency materials also make  
12 clear that such liability extends for only 18 months  
13 following the cancellation of the distributor  
14 registration.

15 MS. GESALMAN: Thank you very much for  
16 your comments.

17 If anyone else has unmuted their line,  
18 please remute yourself.

19 The next person is Jeannie Economos. Please unmute.

20 MS. ECONOMOS: Can you hear me?

21 MS. GUESSELMAN: Yes. Please start.

22 MS. ECONOMOS: This is Jeannie Economos from  
23 the Farmworker Association of Florida.

24 There would be no farms if there were no



1 farmworkers. The majority of the public in the United  
2 States would not have food to eat if there were no  
3 farmworkers in the fields harvesting the food that all  
4 the rest of us eat. Yet, in order to get that food to  
5 our table, farmworkers have to put their lives at risk  
6 every day in the fields from multiple hazards in the  
7 workplace, especially from exposure to pesticides.  
8 Farmworkers are the most vulnerable in our community,  
9 and they deserve our attention and respect.

10 In regards to regulations, I would like  
11 people to come here and sit in our office where every  
12 day we see farmworkers coming into our office. I have  
13 to sit face to face with farmworkers and look them in  
14 the eye and tell them that there's nothing I can do  
15 because the rules are not strong enough to protect  
16 them.

17 Farmworkers who tell me that their children  
18 were born with learning disabilities, with ADHD, with  
19 other behavioral and neurological problems because of  
20 exposure to pesticides, I have to tell them that the  
21 cost to their children is a benefit to the industry.  
22 That is not acceptable.

23 In regards to the designated representative  
24 provision in the WPS, Florida has had a Florida right-  
25 to-know law in the state of Florida since 1994 and

1 '95, and there has never been any cases of any issues  
2 that the farm bureau is concerned about in terms of  
3 any kind of retaliation or problems to farmers because  
4 of the Florida right-to-know law. So, that shows that  
5 it's possible to have it nationwide, and the fears  
6 around the designated representative are unfounded.

7 So, I just wanted to say that we need to  
8 keep the protections of the farmworker protection  
9 standard and the designated representatives and also  
10 the strengthened certified applicator regs, because I  
11 work with farmworkers every day. Our organization is  
12 a grassroots organization. We see farmworkers in our  
13 offices all the time, and we see firsthand the effects  
14 of both short term and long term effects of pesticides  
15 on farmworkers.

16 When we're discussing these regulations, we  
17 need to think about the next generation and the costs  
18 to our healthcare, our public health, from the effects  
19 of pesticides. We're not even talking about long-term  
20 consequences and combinations of pesticides because  
21 farmworkers are exposed all the time.

22 We need stronger protections. Farmworkers  
23 deserve stronger protections. Anybody that eats --

24 MS. GESALMAN: Thank you very much for  
25 your comments.

1           The next person on the list is Antonio Tovar.

2       Antonio, are you there?

3           (No response.)

4           MS. GESALMAN:   Okay, the next person on  
5       the list is Tim Creger.

6           MR. Creger:   This is Tim.   Can you hear me?

7           MS. GESALMAN:   Yes.

8           MR. Creger:   Hi, this is Tim Creger.   I'm  
9       with the Nebraska Department of Agriculture.   I'm a  
10      past president of AAPCO, which Liza Fleeson currently  
11      is representing on the PPDC.   I want to make four  
12      comments, first a general comment to the Office of  
13      Policy, and then I want to address specific examples  
14      of burdensome regulations, experience that we've  
15      experienced on the state level, and past attempts at  
16      reducing regulation that did not result in the  
17      anticipated benefits, then again a cooperative  
18      federalism, which has not been addressed too much in  
19      any of the comments today.

20           First, specific to the Office of Policy at  
21      EPA, I just would like to have them understand how  
22      FIFRA is different than most of the other federal  
23      environmental laws that EPA administers.   When we talk  
24      about federal regulation of pollutants, programs such  
25      as TSCA, Clean Air, Clean Water, those programs are

1 designed to remove or eliminate pollution from the  
2 environment that impacts our human health.

3 When it comes to FIFRA, however, it's  
4 important to realize and understand that federal law  
5 actually requires EPA to not only protect human health  
6 in the environment, but it also requires them to  
7 ensure that there are safe and effective pesticides  
8 available to the consuming public.

9 It's not to argue the benefits of the  
10 pesticides, but it is to argue that -- it's important  
11 to remember FIFRA does allow for those toxicants to be  
12 placed in the environment. They need to be regulated  
13 appropriately.

14 When I address burdensome regulations, I  
15 think it's important to understand that state lead  
16 pesticide agencies such as ours rely heavily on the  
17 financial and knowledge support that we receive from  
18 EPA. However, since 2009, funding from Congress has  
19 been static or reduced to state agencies, as well as  
20 to those universities that conduct pesticide  
21 applicator education.

22 The recent revisions to three of the major  
23 regulations has effectively increased the work burden  
24 on the state lead agencies, while realizing less money  
25 to support them. Those regulations are the container

1     containment regulations, Section 19 of FIFRA, the  
2     Worker Protection Standard rule, and the Certification  
3     and Training rule.

4             Addressing experiences in the past that have  
5     not resulted in what the intended effect was, previous  
6     regulatory reduction programs EPA has attempted have  
7     resulted in significant increased impacts to state  
8     lead agencies.

9             As indicated by the gentleman from Purdue  
10    University, actions by EPA to exempt numerous active  
11    ingredients under section 25(b) of FIFRA has resulted in  
12    a patchwork of state regulation that is nearly  
13    impossible for industry and the public to understand  
14    or navigate.

15            It should be noted that in the absence of  
16    federal regulation, states are faced with the decision  
17    to either exempt or further regulate those pesticides  
18    creating that patchwork of different regulations on the  
19    state level.

20            MS. GESALMAN: Thank you very much for  
21    your comments. If you have further comments,  
22    everybody is reminded to put them in the docket, which  
23    you have information through the various resources  
24    that we have.

25            The next person on the list is Carrie Hugo.

26            MR. TOVAR: Hello, can you hear me now?

1 MS. GESALMAN: Yes, we can hear you.

2 MR. TOVAR: Yes, this is Antonio Tovar.

3 Sorry, I was trying to unmute my phone before.

4 MS. GESALMAN: Is this Antonio?

5 MR. TOVAR: Yes.

6 MS. GESALMAN: Okay, great, thank you.

7 MR. TOVAR: Okay, thank you. So, until last  
8 fall, I was the pesticide (inaudible) investigator for  
9 the Florida Department of Health. Full disclosure, this  
10 position was funded by EPA. So, I'm talking on a  
11 personal behalf. I'm not talking about the Department  
12 of Health. As I mentioned, I just end my work in  
13 there.

14 But I've been working for farmworkers for 10  
15 years. I work with the population as an educator, as  
16 a researcher, as an epidemiologist. EPA has been an  
17 important source of data for me for all these years as  
18 a guidance for the regulations that look for the well  
19 being of workers, residents, and the environment. I'm  
20 disheartened by the proposed changes.

21 Many before me have mentioned the scientific  
22 value you provide and how these knowledge guide most  
23 of the EPA regulations. So, I want to focus a little

1 bit on the cases that I investigated.

2 During my time at the Department of Health,  
3 I investigated several cases of workers or residents  
4 in rural areas, many times not for bravery but because  
5 they end up in the hospital with the damaging effects of  
6 pesticides. Many of these cases demonstrate the alleged  
7 violations of workers' protections and improper use of  
8 pesticide, neglect and even cases of retaliation by  
9 growers and even the pesticide producers and lack  
10 complete disregard for environment.

11 Without the EPA regulations, we'd all be  
12 more vulnerable in this regard for what's happening.  
13 So, I would like to propose these kind of changes.  
14 Thank you.

15 MS. GESALMAN: Great, thank you for your  
16 comments.

17 The next person on the list is Carrie Hugo.  
18 You can unmute. Press pound 6 to unmute, Carrie.

19 (No response.)

20 MS. GESALMAN: Okay, Diane Boesenberg, you can  
21 unmute.

22 MS. BOESENBERG: This is Diane. Can you  
23 hear me?

24 MS. GESALMAN: Yes, I can. Go ahead.

25 MS. BOESENBERG: Okay, great. So, my name

1 is Diane Boesenberg. I'm the Director of Regulatory  
2 and Government Affairs at Reckitt Benckiser. As a global  
3 manufacturer of end use products in the antimicrobial  
4 space and also with a line of products that work with  
5 the FDA, we see a lot of areas for improvement with  
6 regulatory reform. This includes looking outside the  
7 current EPA process for best practices, which will  
8 lead to efficiency and resource savings opportunities,  
9 leaving the EPA with time to do other things.

10 In addition to the comments already made on  
11 questions of jurisdiction, we intend to put these  
12 comments and some others into the official regulatory  
13 reform process.

14 Some of the things that we see that could  
15 save resources and time significantly is, again, to  
16 look outside of the current process. For example, the  
17 FDA has a note to file process which eliminates the  
18 need to submit every single piece of paper to the FDA.  
19 Those changes to registration on the FDA side get  
20 caught up in audits or future registration  
21 submissions.

22 We think the EPA could benefit from looking  
23 at some of the FDA processes. This could be used, for  
24 example, for notifications, non-notifications, supplier  
25 changes on CSFs. Also, Canada has a monograph process



1     for antimicrobials where a particular active  
2     ingredient has been studied for so long that claims to  
3     be made without the need for data to be submitted to  
4     the Agency when a product contains a specific active  
5     at a predetermined level. So that could be also a  
6     very useful process.

7             We also see the need for better clarity for  
8     OECD and U.S. EPA GLP harmonization where studies could  
9     be done at labs globally for a global company like  
10    ours that could be submitted to the EPA without the  
11    need for doing additional testing.

12            Also, we'd like to see something about  
13    mutual recognition of data generated by published  
14    antimicrobial efficacy methods for global product  
15    registration without the need for additional EPA  
16    review of the published methods. There are lots of  
17    examples where this could save significant time and  
18    resources on the Agency's part.

19            Then, finally, harmonization of federal EPA  
20    reviews and California reviews, so not only is that a  
21    federal savings, but it also saves times at the  
22    states.

23            So, again, we really see areas for  
24    harmonization and efficiency at the Agency level to  
25    help us with some of the other time line issues, you

1 know, processing of PRIA applications in a more  
2 efficient and timely way, and hope that we can help in  
3 that space. Thank you.

4 MS. GESALMAN: Thank you very much.

5 The next person on the list is Dave Tamayo.  
6 Please unmute by pressing pound 6. Dave?

7 (No response.)

8 MS. GESALMAN: Okay, Mary Lamielle.  
9 Are you on the line, Mary? Mary Lamielle. Press pound 6.

10 (No response.)

11 MS. GESALMAN: Okay, Karin North, please  
12 press pound 6 to unmute.

13 MS. NORTH: This is Karin North.

14 MS. GESALMAN: Great, hear you. Go ahead.

15 MS. NORTH: Hi, this is Karin North. I am  
16 the watershed protection manager for the city of Palo  
17 Alto. I just wanted to comment and thank you so much  
18 for allowing comments from California. But we  
19 appreciate the Environmental Protection Agency's goals  
20 to safeguard human health and the environment.

21 I'm giving a different perspective from the  
22 regulated community wearing the stormwater and a  
23 wastewater perspective. So, we actually need to make  
24 sure that our waterways are safe from aquatic --

1 protect the environment and -- sorry, I've been up  
2 since very early this morning -- but to protect the  
3 environment and ensure that the aquatic organisms are  
4 safe.

5           So, we actually rely heavily on the  
6 Environmental Protection Agency's regulations on  
7 pesticides to ensure that we don't have toxicity in  
8 our wastewater that gets discharged out into the San  
9 Francisco Bay, and also that we're not causing  
10 Non-point source pollutant toxicity into stormwater. So,  
11 we actually think that there needs to be more  
12 regulations to improve and enhance the protection of  
13 the aquatic organisms.

14           We also support the safeguarding of human  
15 health. We really need you as a partner agency  
16 because many things we're regulated on that we cannot  
17 actually do anything. But we need EPA to help ensure  
18 that the pesticides being applied are not going to  
19 cause toxicity. The city also has an integrated pest  
20 management policy, so we try and use the least toxic  
21 pests obviously rather than the toxic ones.

22           Anyway, we will submit lengthy comments on  
23 behalf of the stormwater and the waste water community  
24 in Palo Alto. Thank you again.

25           MS. GESALMAN: Okay, thank you very much.

1           The last call for Carrie Hugo, Dave Tamayo,  
2           or Mary Lamielle?

3           MR. TAMAYO: This is Dave Tamayo. Can you  
4           hear me?

5           MS. GESALMAN: Yes, we can.

6           MR. TAMAYO: Oh, good. I finally figured  
7           out how to get back to that screen.

8           Hi, I'm Dave Tamayo. I'm with the  
9           California Stormwater Quality Association, otherwise  
10          known as CASQA. I just wanted to thank you for this  
11          opportunity and also say hello to many of the people I  
12          served with on PPDC for six years. Thank you for this  
13          opportunity.

14          You know, as we've mentioned many times over  
15          the last 20 years in commenting to EPA, the stormwater  
16          agencies in California that represent and that serve  
17          the vast majority of California residents have been  
18          saddled with the effects of currently registered  
19          pesticides that are used in urban areas that impact  
20          urban water quality.

21          Because it's observed throughout the state  
22          and because we have obligations to comply with Clean  
23          Water Act permits, we've been saddled with costs for  
24          monitoring, tracking registration activities, trying  
25          to influence how pesticides are registered, and,

1     ironically, trying to convince consumers and licensed  
2     users that they need to be more careful of how to use  
3     beyond what the label requires to prevent water  
4     quality impacts.

5             We learned early on in the process that both  
6     consumers and licensed users rely on the assumption  
7     that products that are registered by EPA and used the  
8     way they're supposed to be used will be sufficiently  
9     protective of the environment. Unfortunately, in many  
10    important cases in urban areas, that is not yet the  
11    case.

12            I do want to acknowledge that EPA has made  
13    some significant efforts and improvements in that  
14    area, but there's still some important areas that  
15    would help reduce the regulatory burden and economic  
16    burden on local and state agencies here.

17            One is that EPA needs to implement the use  
18    of models and realistic model parameters that  
19    adequately predict the fate and transport and impacts  
20    of urban use pesticides.

21            We also support the need to develop a more  
22    efficient system for working through the requirements  
23    of the Endangered Species Act. An essential tool for  
24    that would be to require a set of aquatic toxicity  
25    data that's robust enough to support a high level of

1 confidence among the various stakeholders that the  
2 toxic effects are adequately identified, which would  
3 lead to more rational registration decisions and  
4 mitigation requirements that arise from that.

5 Finally, we want registration decisions to  
6 include economic impacts on folks that are sort of  
7 downstream of the users. You know, we have some  
8 direct clean water act economic impacts on both  
9 state and local agencies. Those can be very  
10 significant. It can cost between half a million and a  
11 million dollars to do one TMDL in a watershed area.  
12 As I said, there's impasse throughout the state.

13 We also believe that the consideration of  
14 underlying ecological effects that affect beneficial  
15 uses need to be part of the economic analysis that's  
16 done when making registration decisions. And if these  
17 things are done well and robustly enough, then that  
18 would be an important part of achieving predictability  
19 and consistency in regulation.

20 MS. GESALMAN: Thank you for your  
21 comments.

22 Is Carrie Hugo or Mary Lamielle on the phone?  
23 Either one of you can press pound 6 to unmute.

24 (No response.)

25 MS. GESALMAN: It sounds like that

1 concludes the telephone portion of this program.

2 MR. KEIGWIN: Thanks, Claire. We did have a  
3 couple of additional people sign up to speak that just  
4 came to my attention. So, Dudley Hoskins from NASDA.

5 MR. HOSKINS: Thanks, Rick. I'm going to  
6 start my timer, so hopefully I won't go over three  
7 minutes.

8 First off, my name is Dudley Hoskins. I'm  
9 with the National Association of State Departments of  
10 Agriculture. Our members are the commissioners,  
11 secretaries, and directors in all 50 states and four  
12 territories. In 43 states, the state department of ag is  
13 the lead FIFRA state agency. So, in short, we're  
14 regulatory partners with EPA. For us, it's a really  
15 critical partnership, and we really appreciate both  
16 the work here at OPP headquarters and the work that  
17 goes on around the regions.

18 So, NASDA will be submitting comments to the  
19 docket, EO 1377. They will be more comprehensive and  
20 hopefully more articulate than what I'm going to blast  
21 through real quick right here. But just a few things  
22 we wanted to touch on, put forth for the Agency to  
23 hopefully consider some regulatory assistance on.

24 The first one is the certification and

1 training of pesticide applicators. I want to note  
2 that at NASDA, we greatly appreciated all the work and  
3 improvements that EPA invested into that rule. What  
4 came out as the final regulation is something we were  
5 very supportive of. There's probably one provision  
6 there we'd like to work with the Agency on to see if  
7 we can modify how that's written. But, by and large,  
8 we really appreciate the work that went into that.

9 We've joined a couple other groups, AAPCO,  
10 ASPCRO, and some of the regulated community in asking  
11 EPA to extend the effective date of that rule. Just  
12 by and large, states across the board, we have a lot  
13 of logistical resource and capacity challenges, and  
14 additional time to work through this would be greatly  
15 appreciated.

16 I should have noted, as part of the NASDA  
17 family, we have 23 affiliate organizations. Several  
18 of those are represented here in the PPDC and work  
19 closely with EPA. Both AAPCO, the American  
20 Association of Pesticide Control Officials, ASPCRO,  
21 the American Association of Structural Pesticide  
22 Regulatory Officials, the National Plant Board, and  
23 the Apiary Inspectors in America are all groups who  
24 work closely around the FIFRA mission areas.

25 I would like to thank Liza for her



1 leadership on a number of these fronts, and Tim Creger  
2 from the Nebraska Department of Ag who called in.

3 Just quickly, under the Worker Protection  
4 Standard, we have a request pending with the Agency  
5 requesting additional time on the implementation of  
6 that regulation. We would really appreciate EPA  
7 considering that request.

8 In addition to needing more time around the  
9 implementation, we would love to have the opportunity  
10 to revisit a few specific provisions in that rule  
11 around the designated representative and the  
12 application exclusion zone. Both of those, for our  
13 purposes, are really challenging to better understand  
14 and assist with compliance assistance, education  
15 enforcement components.

16 I'm over time, I'm sorry. I just wanted to  
17 mention, on the pollinator front, I really appreciate  
18 all the great work that OPP has done and the  
19 leadership that you all have invested in that in the  
20 state managed pollinator protection plans. I really  
21 look forward to working with you all to stand those  
22 up.

23 A robust, well-funded, and fully staffed OPP  
24 is something that NASDA is very supportive of, and we  
25 really appreciate the work you all do. Thank you for

1 the opportunity to comment.

2 MR. KEIGWIN: Are there others in the room  
3 who haven't had an opportunity to speak? Please come  
4 sit by the microphone and identify yourself.

5 MS. BADEN-MAYER: My name is Alexis Baden-  
6 Mayer. I'm the political director of the Organic  
7 Consumers Association.

8 This is not a normal EPA hearing. We're  
9 here today because Trump and Pruitt have invited the  
10 companies that sell toxic pesticides to tell the EPA  
11 which regulations to get rid of. It's not normal, and  
12 it's not legal. The EPA's Office of Pesticide  
13 Programs has the duty to preserve and enforce the laws  
14 Congress passed to protect human health and the  
15 environment.

16 Chemicals found in plastic bottles, flame  
17 retardants, metal food cans, detergents, cosmetics,  
18 and pesticides cost the U.S. more than \$340 billion a  
19 year in health costs and lost earnings.  
20 Organophosphate pesticides are associated with 1.8  
21 million lost IQ points and 7,500 cases of intellectual  
22 disability in the U.S. each year, at an estimated cost  
23 of \$44.7 billion dollars. Economic and social costs of  
24 pesticide exposure are devastating.

25 Harmful chemicals should be banned, not

1 deregulated. The EPA must put American's health above  
2 Dow Chemical's wealth. The EPA must protect us. Don't  
3 let Trump make us sicker so that his corporate donors  
4 can get richer. Trump is America's first billionaire  
5 president. Corporations are seeing an unprecedented  
6 opportunity to merge their power with the government.

7 As Senator Sheldon Whitehouse said recently,  
8 while Trump is president, the various checks and  
9 balances of the American system must do their part to  
10 check Trump and corporate influence. Senator  
11 Whitehouse said, "If it fails, this could be Mussolini  
12 time in America, and that would not be good."

13 On the that would not be good side is Dow  
14 Chemical. In Trump's first three months, Dow Chemical  
15 spent \$5.2 million dollars on lobbying, making it the seventh  
16 biggest spender among all corporations by influence in  
17 Washington. At \$13.5 million dollars a year, or actually in  
18 2016, sorry, Dow's lobbying expenditures topped all of  
19 its competitors, including Bayer, DuPont, Monsanto,  
20 and Syngenta. Dow also donated \$1 million dollars to Trump's  
21 inauguration.

22 Being a big spender has given Dow  
23 extraordinary access to the administration. CEO  
24 Andrew Liveris was appointed to head a  
25 White House manufacturing council. After Trump signed

1 the executive order to roll back regulations, he  
2 handed the pen to Liveris.

3 Greasing palms is just the cost of doing  
4 business for Dow, and a relatively minor one. The  
5 company reported \$888 million dollars in net income for the  
6 first quarter of 2017 in its April 27th earning  
7 statement. Money talks; children's health walks.

8 Under Obama, Dow was going to have to stop  
9 selling chlorpyrifos, a pesticide that inhibits brain  
10 development with effects ranging from lower IQ rates  
11 to autism. But, under Trump, the decision was  
12 reversed. We cannot have the health of future  
13 generations stripped from us just so that Dow can meet  
14 its short term profit goals. The employees of the EPA  
15 must resist Trump before it is too late. We cannot  
16 let Trump get rid of regulations to protect human  
17 health from toxic pesticides.

18 Unfortunately, the merger of corporate and  
19 government power at the EPA did not begin with Trump.  
20 Through a lawsuit on behalf of glyphosate exposed  
21 cancer victims, we learned that Anna Lowit,  
22 currently at the Office of Pesticide Programs --

23 MR. KEIGWIN: Time.

24 MS. BADEN-MAYER: -- was accused by a  
25 colleague of intimidating EPA scientists --

1 MR. KEIGWIN: I'm sorry.

2 MS. BADEN-MAYER: -- and changing the  
3 outcome of EPA reviews to favor companies like  
4 Monsanto. My request to all current EPA employees is  
5 this. Leave the laws that Congress passed to protect  
6 human health and the environment and enforce them.  
7 Resist Trump's arbitrary and capricious edicts. He is  
8 not a dictator yet. We still have regulatory agencies  
9 staffed by scientists and qualified professionals. Do  
10 your job. Speak out. Blow the whistle if you have  
11 to. The future of butterflies, bees, and babies  
12 depend on you.

13 UNIDENTIFIED FEMALE: I'm so sorry, but  
14 we've reached the end of your time.

15 MR. KEIGWIN: Are there any other speakers  
16 in the room?

17 (No response.)

18 MR. KEIGWIN: Peter, I think you had wanted  
19 to finish your remarks, so you can come forward.

20 MR. JENKINS: After the last speaker's eloquence,  
21 mine is a bit more mundane. Again, I'm trying to see  
22 the questions that were in the EPA's announcement and  
23 identify useful questions that were raised. So, one  
24 of them was, which regulations are based on data,  
25 information or methods that are not publicly available

1 or that are insufficiently transparent. I think we'll  
2 be able to identify a number of such regulations.

3 But the one that I'm going to focus on here  
4 is really an obscure one but really an important one.  
5 It's 50 CFR 158.400(e)(1), really buried in your  
6 regulations. It's one that says that for pesticide  
7 applicants, people that are trying to get approval for  
8 a new registration, it says the Agency has waived the  
9 requirement to submit product performance data, with a  
10 few exceptions. Agency is not requiring product  
11 performance data.

12 I don't know when that was implemented. I  
13 think it was about 10 or 15 years ago, but the Agency  
14 used to require transparency about product performance  
15 so people could FOIA that and we could have access to  
16 whether these products really worked as claimed. But  
17 the Agency no longer requires that.

18 Well, the most absurd result of that is that  
19 with respect to insecticide seed coatings on soybean  
20 seeds, in 2015, EPA did a detailed, costly, public  
21 paid benefits assessment and determined that actually  
22 seed coatings on soybeans provided no benefits to  
23 farmers on the whole, very little, if any, was, I  
24 think, the exact words from EPA's assessment.

25 It's been backed up by several other

1 independent assessments, including one by the Center  
2 for Food Safety. So, that was 15 years after it first  
3 allowed seed coatings to go onto soybean seeds, or at  
4 least 12 years after. So, we, as a nation,  
5 experienced 10 or 15 years of these products that  
6 actually provide no benefit because of this obscure  
7 regulation that allowed the applicant to not have to  
8 provide performance data. Do you see what I'm getting  
9 at?

10 So, cost benefit analysis is part of what  
11 the Trump executive order is asking for. It's good  
12 business to be cost beneficial. So, the Agency should  
13 not be allowing pesticide products to go into the  
14 market that provide no ultimate benefit to the users.  
15 So, the farmers are getting ripped off. It's a big  
16 consumer protection scandal in my opinion, for the  
17 farmers are getting ripped off by these products.

18 We, as environmentalists, as bird lovers, as  
19 beekeeper supporters, are getting harmed by the side  
20 effects of these products. So, that's the end of my  
21 comments. Thank you.

22 MR. KEIGWIN: Are there any other commenters  
23 in the room?

24 (No response.)

25 MR. KEIGWIN: Bill, I know you had wanted to

1 say a little bit more as well.

2 MR. JORDAN: Thank you. My name is Bill  
3 Jordan.

4 I just want to take a moment to say that I  
5 know two of the individuals who have been mentioned,  
6 Jess Rowland and Anna Lowit, as employees of EPA whose  
7 integrity has been challenged in comments made this  
8 morning. I know both of them well, and I think those  
9 comments are completely unfounded.

10 Those two individuals, like many, many, many  
11 other people who work in the Office of Pesticide  
12 Programs, maintain a high standard of integrity,  
13 competence, and commitment to the work of the Agency.  
14 It is disrespectful and shameful, in my opinion, to  
15 criticize them in that manner.

16 MR. KEIGWIN: I think I see one last  
17 commenter.

18 MS. WALKER: Hi, I'm Larissa Walker and I'm with  
19 the Center for Food Safety. I wanted to provide a quick  
20 comment today to stress the importance of EPA's mandate  
21 to protect human health and the environment and encourage  
22 EPA to uphold and strengthen many of the key regulations that  
23 are intended to support the Agency's core mission,  
24 regulations that protect farmworkers, as we heard



1 today, children, pregnant women, vulnerable  
2 communities, endangered species, pollinators, our  
3 water, our air, and the broader environment, all of  
4 which are threatened by the rampant use of toxic  
5 pesticides, pesticides that EPA is obligated to  
6 protect against unreasonable adverse harm from.

7 So, I want to echo many of the important  
8 comments today made by my colleagues and urge EPA to  
9 uphold its commitment to human health and the  
10 environment and not weaken or completely throw away  
11 critical regulations that protect us against serious  
12 harms from pesticides. Thank you.

13 MR. KEIGWIN: Thank you. I think I see one  
14 more hand here, if you want to come up to the  
15 microphone. Please introduce yourself.

16 MR. PETERS: Hello, my name is Joshua Peters  
17 (phonetic). I'm not with any agency. I'm a former  
18 school teacher of 13 years. As part of my training, I  
19 traveled to different countries. In 1996, I was in  
20 Guatemala. I visited many of the outlying areas  
21 around the capital. In a place that was just coming  
22 out of a really tumultuous period, there was very  
23 little regulation.

24 A scene that has always stuck out in my  
25 memory was playing soccer with a group of what I

1     thought were children all around my hip height -- me  
2     being a short person, that's not very tall -- only to  
3     find out that these were children in their 20s and who  
4     have all been victims of rampant dumping of chemical  
5     waste and toxicity.

6             I've always looked towards the EPA as an  
7     agency that ultimately has humanity's best interest at  
8     heart. The son of a physicist who spent his last 15  
9     years working for NOAA and a family generally  
10    committed towards working towards human good, I'd  
11    hoped that this organization had the wherewithal and  
12    character to stand up for what is scientifically  
13    correct and morally right for the United States  
14    population.

15            MR. KEIGWIN: One last call for speakers in  
16    the room.

17            (No response.)

18            MR. KEIGWIN: All right, thank you for all  
19    of you who participated today. This closes our public  
20    comment session of the PPDC meeting.

21            Just to wrap things up, as far as it goes  
22    for the PPDC meeting, just a reminder that the public  
23    comment period on the executive order and the  
24    implementation here at EPA closes on May 15th of this  
25    year.

1           As we mentioned at the beginning of the  
2 meeting, there will be a transcript available from  
3 this morning's discussion, available on the PPDC  
4 website within the next couple of weeks.

5           As I mentioned yesterday, we have just  
6 completed a new membership drive for the Pesticide  
7 Program Dialogue Committee. We'll soon be reviewing  
8 the nominations that came forward and making a  
9 recommendation internally through the Agency. Over  
10 the next few months, we will be announcing the  
11 reconstituted membership of the Pesticide Program  
12 Dialogue Committee.

13           For all of you, the next PPDC meeting is  
14 scheduled for November 1st and 2nd of this year.

15           Then, before we conclude, I just want to  
16 give several mentions of thanks, first to the PPDC  
17 members for all of your efforts. We had a great  
18 dialogue yesterday, and I think we got some valuable  
19 input from you all as we think about how we advance  
20 some of the issues that we brought to you.

21           And for the members of the PPDC who have  
22 been term limited, I really want to thank you for your  
23 dedication over the last six years. We get a lot out  
24 of the work that you all do, and we know that you have  
25 other jobs that you're doing. So, squeezing in the

1 time to provide input to us is invaluable. So, thank  
2 you for that.

3 I also really want to thank Dea Zimmerman  
4 for all of her help. When we learned of the need to  
5 hold the public meeting regarding the executive order  
6 and we scrambled given the time frame that we had, we  
7 knew we had this opportunity to PPDC. Rather than  
8 seeing it as a challenge, Dea just really ran with it.  
9 I think she spent about three or four Monday mornings  
10 with us, calling in from Chicago, while we were all  
11 trying to figure out how do we do this. She had the  
12 clarity of sight to kind of figure it out and get it  
13 done right and pull together really an army of people  
14 from across the Office of Pesticide Programs to get  
15 this to run as smoothly as it did. So, I just want to  
16 thank Dea personally.

17 We also got a lot of assistance from our  
18 colleagues in Office of Land and Emergency Management  
19 in terms of trying to figure how to run today's  
20 meeting in particular and how to get as many of you in  
21 the room as possible, how to run the phone lines. We  
22 couldn't have pulled this off without the efforts of  
23 our sister office. So, thank you to our OLEM colleagues  
24 as well.

25 And then, again, thank you to all of you for

1 participating. This concludes the PPDC meeting.

2 Thank you, and have a good rest of the day.

3 (The meeting was concluded.)

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